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IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

JENNIE R. LEFEVRE, SALLY M. HILL,
FREDERICK L. RADA AND MARY CHRISTINA VELDMAN,
Petitioners,

v.

SECRETARY, DEPARTMENT OF VETERANS AFFAIRS,
Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Agent Orange Act of 1991 requires the Secretary of Veterans Affairs, in deciding eligibility for veterans' disability and death benefits, to consider "sound medical and scientific evidence" in determining whether a "positive association" exists between "the exposure of humans to an *herbicide agent*" and "the occurrence of a disease in humans," 38 U.S.C. § 1116(b)(1) (emphasis added). The questions presented in this case are:

1. Whether, once the Federal Circuit determined that the Secretary of Veterans Affairs' denial of a positive association and presumptive service connection for prostate cancer rested on findings not supported by, and contrary to, the record, the court should have vacated the Secretary's rule and remanded the case for reconsideration rather than upholding the Secretary's rule on bases not relied on by the Secretary.

2. Whether the Act permits the Secretary to ignore credible evidence of an association between exposure to dioxin, which is indisputably an "herbicide agent," and disease in humans simply because dioxin is not, in and of itself, an herbicide.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Jennie R. LeFevre, Sally M. Hill, Frederick L. Rada and Mary Christina Veldman respectfully petition for a writ of certiorari to review the judgment and opinion of the United States Court of Appeals for the Federal Circuit ("Federal Circuit").

OPINIONS BELOW

The opinion of the Federal Circuit (App. 1a-27a),[1] entered on September 15, 1995, is reported at 66 F.3d 1191 (Fed. Cir. 1995). The administrative rule under review (App. 28a-45a), issued by the Secretary of Veterans Affairs, is reported at 59 Fed. Reg. 341 (1994).

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[1] All citations to "App. ——" refer to the Appendix filed contemporaneously herewith pursuant to United States Supreme Court Rule 14(1)(i). All citations to "Jt. App. ——" refer to the Joint Appendix filed in the proceedings before the Federal Circuit.

JURISDICTION

The judgment of the Federal Circuit was entered on September 15, 1995. App. 1a-27a. A petition for rehearing was denied on October 13, 1995. App. 46a. On December 12, 1995, the Chief Justice extended the time for filing this petition to and including February 12, 1996. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The Agent Orange Act of 1991, Pub. L. No. 102-4, § 2, 105 Stat. 11 (1991) (codified as amended at 38 U.S.C. § 1116) (including relevant portions of the Historical and Statutory Notes thereto); and the administrative rule under review, reported at 59 Fed. Reg. 341 (1994), are reprinted in the Appendix beginning at App. 47a and 28a, respectively.

STATEMENT OF THE CASE

1. The four petitioners are a Vietnam veteran who has prostate cancer [2] and three widows of Vietnam veterans who died from hepatobiliary (liver and bile) cancer or nasal/nasopharyngeal ("nasal") cancer.[3] Petitioners

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[2] Petitioner Frederick Rada currently suffers from prostate cancer. He has applied to the Department of Veterans Affairs ("VA") for disability benefits for such cancer, but his claim will presumably be denied because of the denial by the Secretary of Veterans Affairs ("Secretary") of presumptive service connection for prostate cancer in the January 4, 1994 rule at issue herein.

[3] Petitioners Jennie LeFevre and Sally Hill are the widows of veterans who died from hepatobiliary cancer or complications related thereto. Under current veterans law, a surviving spouse is entitled to Dependency and Indemnity Compensation ("DIC") if his or her spouse dies as a result of a service connected condition. 38 C.F.R. § 3.5. Both petitioners have applied to the VA for DIC benefits based on their spouses' death from hepatobiliary cancer. Petitioner LeFevre's claim for DIC has already been denied because of the Secretary's denial of presumptive service connection for hepatobiliary cancer. Petitioner Hill's DIC claim

allege that the veterans' cancers were associated with exposure to herbicide agents during their military service in Vietnam and that, accordingly, they are entitled to disability or death benefits from the Department of Veterans Affairs ("VA"). Under Section 2 of the Agent Orange Act of 1991, 38 U.S.C. § 1116 (the "Agent Orange Act" or "Act"), the Secretary of Veterans Affairs ("Secretary") is required to grant presumptive service connection for diseases for which he determines there is a "positive association" between the diseases and exposure to an "herbicide agent," *i.e.*, any chemical in an herbicide used in Vietnam. 38 U.S.C. § 1116(a)(4), (b)(1). This case involves the petitioners' challenge to the Secretary's rule, issued January 4, 1994, denying a positive association and presumptive service connection for prostate cancer, hepatobiliary cancer, and nasal cancer.

2. The Agent Orange Act represents the second attempt by Congress to ensure compensation for Vietnam veterans and their families for harm suffered as a result of the veterans' exposure to dioxin contained in herbicides, including principally "Agent Orange," [4] during their military service in Vietnam. Within the last ten years, Congress has twice enacted major statutes to compel the Secretary (formerly Administrator) of Veterans Affairs to (1) determine which diseases are associated with exposure to dioxin and other chemical agents found in

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presumably will be denied likewise because of the Secretary's denial of presumptive service connection for hepatobiliary cancer.

Petitioner Mary Christina Veldman's husband died from nasal cancer or complications related thereto. She applied for DIC benefits based on her spouse's death from nasal cancer. Her claim was denied by the Regional Office and is pending on appeal before the Board of Veterans' Appeals. Her claim presumably will be denied because of the Secretary's denial of presumptive service connection for nasal cancer.

[4] "Agent Orange" is a 50/50 blend of 2,4-Dichlorophenoxyacetic Acid (2,4-D) and 2,4,5-Trichlorophenoxyacetic Acid (2,4,5-T). The chemical processes of making 2,4,5-T created some amount of 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin ("dioxin").

herbicides used by American military forces in Vietnam; and (2) to pay compensation to Vietnam veterans or their survivors for disabilities associated with those diseases.

First, in 1984, Congress enacted the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, Pub. L. No. 98-542, 98 Stat. 2725, 2727 (1984) (amended by Pub. L. No. 102-4, § 10(a), (b), 105 Stat. 19 (1991)), which directed the Secretary to grant presumptive service connection "to veterans who were exposed during service . . . in the Republic of Vietnam to a herbicide containing dioxin" for any disease which "sound scientific and medical evidence" demonstrates is "connected . . . to such service." The VA construed the 1984 statutory standard as demanding proof of a " 'cause and effect relationship between dioxin exposure' and any diseases," *Nehmer* v. *United States Veterans' Admin.*, 712 F. Supp. 1404, 1416 (N.D. Cal. 1989) (quoting 35 C.F.R. § 3.311(d)), before VA was required to presumptively connect such a disease to military service. Under the VA's restrictive causal relationship requirement, VA found only one disease to be service connectable—chloracne. *Id.* at 1408. In 1989, the VA's "cause and effect" requirement was judicially invalidated. See *id.* at 1423. Instead, it was held that Congress intended to require only that there be "a finding of a significant statistical association between dioxin exposure and various diseases" to mandate presumptive service connection. *Id.* at 1420.

In 1991, frustrated with the VA's restrictive and dilatory implementation of even this less burdensome, "statistically significant association" standard, Congress enacted the Agent Orange Act with an explicitly more permissive legal standard. See 137 Cong. Rec. H730 (daily ed. Jan. 29, 1991) (statement of Rep. Evans); 137 Cong. Rec. S1267 (daily ed. Jan. 30, 1991) (statement of Sen. Daschle). In the Agent Orange Act, 38 U.S.C. § 1116(b), Congress not only omitted any requirement to prove a "cause and effect" relationship as a prerequi-

site to making a disease presumptively service connected, but also eliminated the requirement announced by *Nehmer* to prove a statistically significant association.[5] Instead, by requiring the Secretary to service connect a disease for which he finds a "positive association," *id.* § 1116(b)(1), and deeming a "positive association" to exist whenever "the credible evidence for the association is *equal to or outweighs* the credible evidence against the association," *id.* § 1116(b)(3) (emphasis added), Congress created a strikingly expansive standard for service connection. Congress has not even required that a "preponderance" of the scientific evidence favor an association; rather, as in baseball, where a "tie goes to the runner", here, a "tie" in the scientific evidence "goes to the veterans." *Cf. Gilbert* v. *Derwinski*, 1 Vet. App. 49, 55-56 (1990).[6] Indeed, Congress went so far as to *continue* benefits for veterans and their survivors awarded on the basis of presumptive service connection, even if the Secretary subsequently determines that a presumption is *not* warranted. See 38 U.S.C. § 1116(d).

Under the Agent Orange Act, Congress established a statutory scheme pursuant to which the Secretary was to seek to contract with the National Academy of Science ("NAS"), an independent non-profit, non-governmental scientific organization. NAS was to "review . . . and assess the strength" of the scientific evidence as to the association, if any, between exposure to herbicides used

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[5] While the Agent Orange Act requires the Secretary to "take into consideration" when he "evaluate[s] any study" whether its "results are statistically significant," 38 U.S.C. § 1116(b)(2), along with several other factors affecting how much weight he should give to any study, *id.*, there is no statutory prerequisite that evidence be statistically significant before presumptive service connection is warranted. *Id.* § 1116(b). The Secretary apparently agrees that, under the Act, "statistical significance" is only one factor affecting the weight to be given a study. *See* 59 Fed. Reg. 341, 342 (1994) (App. 30a).

[6] This is in keeping with the congressional recognition of the large debt which the country owes its veterans. *See Gilbert*, 1 Vet. App. at 54.

by American forces in Vietnam and "each disease suspected to be associated with such exposure," 38 U.S.C.A. § 1116 Note, sec. 3(c), and submit periodic reports to Congress on its findings, *id.*, sec. 3(g).

Within 60 days after the Secretary received the NAS's first such report, he was to determine whether a "positive association exist[ed] between (A) the exposure of humans to an *herbicide agent*, and (B) the occurrence of a disease in humans." 38 U.S.C. § 1116(b)(1) (emphasis added).[7] The Secretary had to find that a "positive association" existed "if the credible evidence for the association is equal to or outweighs the credible evidence against the association." *Id.* § 1116(b)(3). Whenever the Secretary found a "positive association," the Act required him to presumptively service connect that disease. *Id.* § 1116(b)(1).[8] However, if the Secretary determined

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[7] Curiously, the language of the Act only obligates NAS to consider evidence of association between "herbicides" and disease, not between "herbicide agents" and disease, 38 U.S.C.A. § 1116 Note, sec. 3(d)(1)(C), as is required of the Secretary under 38 U.S.C. § 1116(b)(1). Notwithstanding this apparent discrepancy between the duties imposed upon NAS and the Secretary, NAS construed its mandate under the Act as being to study "the health effects of exposure to Agent Orange, other herbicides used in Vietnam, *and* their components, including dioxin." Jt. App. 106B (emphasis added). Accordingly, NAS reported on studies concerning exposure both to "herbicides *and* herbicide components." *Id.* at 106D (emphasis added). NAS traced the Act to "public concerns" over, *inter alia*, "environmental and occupational exposure to herbicides and dioxin." *Id.* at 106A. NAS also noted that studies involving exposure to herbicides were not as available as studies involving exposure to TCDD or dioxin. *Id.* at 106C.

[8] The legal effect of granting presumptive service connection for any particular disease was to presume each Vietnam veteran who had such disease to have been exposed to an herbicide containing dioxin in Vietnam, 38 U.S.C. § 1116(a)(3), and to presume that the disease was "incurred in or aggravated by [military] service," *id.* § 1116(a)(1). As a result of these presumptions, each Vietnam veteran who incurred such a disease would be entitled to monthly disability compensation, unless the VA could prove that the disease was due to some cause other than exposure in Vietnam to

that the scientific evidence weighed against a "positive association" as to a particular disease, the Act mandated that he publish within 60 days of this determination a notice in the Federal Register explaining the "scientific basis for that determination." *Id.* § 1116(c)(1)(B).

3. On July 27, 1993, NAS issued its first report pursuant to the Act—Institute of Medicine, National Academy of Sciences, *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam* (Certified List ("C.L.") #2) ("NAS Report") (Jt. App. 106-227). The NAS Report placed various diseases in one of four categories relating to the strength of the evidence of an association between each disease and herbicide exposure. The four categories are "Sufficient Evidence of an Association," "Limited/Suggestive Evidence of an Association," "Inadequate/Insufficient Evidence to Determine Whether an Association Exists," and "Limited/Suggestive Evidence of No Association." Jt. App. 204. Prostate cancer was placed in the second category, "Limited/Suggestive Evidence of an Association," and hepatobiliary and nasal cancer were placed in the third category, "Inadequate/Insufficient Evidence to Determine Whether an Association Exists." [9]

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an herbicide containing dioxin. *See id.* § 1110; 38 C.F.R. § 3.303. In addition, if such a veteran died from his presumptively service connected disease, his survivors would be entitled to death benefits. *See* 38 U.S.C. § 1310.

[9] These two categories are defined as follows:

Limited/Suggestive Evidence of an Association: Evidence is suggestive of an association between herbicides and the outcome but is limited because chance, bias, and confounding could not be ruled out with confidence. For example, at least one high-quality study shows a positive association, but the results of other studies are inconsistent.

Inadequate/Insufficient Evidence to Determine Whether an Association Exists: The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association. For example, studies fail to control for confounding, have inadequate exposure assessment, or fail to address latency.

Jt. App. 204.

4. On December 22, 1993, the Secretary signed a rule concluding that the scientific evidence did not establish a "positive association" as to 20 suspected diseases, purported to explain the scientific bases for those conclusions, and refused to grant presumptive service connection to any of those diseases. On January 4, 1994, pursuant to 38 U.S.C. § 1116(c)(1)(B), the Secretary published the rule in the Federal Register. 59 Fed. Reg. 341 (1994) (App. 28a). The rule, which is the subject of this case, contains the Secretary's determination that there is no "positive association," 38 U.S.C. § 1116(b)(3), between herbicide exposure[10] and 20 diseases suspected of being associated with exposure to herbicides in Vietnam, and his consequent determination that "a presumption of service connection is not warranted," *id.* § 1116(c)(1)(B). Three of the 20 denied diseases—prostate cancer, hepatobiliary cancer and nasal cancer—are at issue here.

a. *Prostate Cancer*

The Secretary found "that the credible evidence against an association between prostate cancer and herbicide exposure outweighs the credible evidence for such an association, and . . . [that] a positive association does not exist." 59 Fed. Reg. at 342 (App. 32a). Notably, prostate cancer is the *only* disease which NAS placed in the second category ("Limited/Suggestive Evidence of an Association") for which the Secretary *denied* a positive association. The other two diseases in that category, respiratory cancer and multiple myeloma, as well as all five diseases placed by NAS in the first category, were granted presumptive service connection. See Jt. App. 106F-106G; 55 Fed. Reg. 43,123, 43,124 (1990) (non-Hodgkin's lymphoma, "NHL"); 56 Fed. Reg. 51,651 (1991) (soft tissue sarcoma, "STS"); 56 Fed. Reg. 29,719, 29,723 (1991).

[10] Notwithstanding the statutory mandate that the Secretary must determine the existence of a "positive association" between exposure to an "herbicide agent" and disease, the Secretary uniformly made his determinations instead based on exposure to an "herbicide" itself. *See* 59 Fed. Reg. at 342-46 (App. 30a-45a).

The central basis for the Secretary's conclusion is his finding that "[t]here are statistically significant occupational studies which show no association between prostate cancer and herbicide exposure." 59 Fed. Reg. at 342 (App. 31a). In support of this finding, the Secretary cited three studies reviewed in the NAS Report—studies by Fingerhut, Manz and Saracci.[11] *Id.* The Secretary balanced the purported conclusions of these three studies against those of "[s]ome occupational studies [that] have shown a slight elevated risk for prostate cancer among farm and forestry workers," [12] and "one study concerning a small sub-set of farmers (Morrison, H., [*et al.*], 1993. Farming and prostate cancer mortality. American Journal of Epidemiology 137:270-280 [C.L. #1.38]) [that] associated the increased risk of prostate cancer among farmers specifically with herbicide exposure." *Id.* (App. 31a-32a). The only other reason the Secretary gave for concluding that the "credible evidence against an association between prostate cancer and herbicide exposure outweighs the credible evidence for such an association," *id.* (App. 32a), was that "[t]he Morrison study is so recent that it it [sic] too early to determine whether its results will be replicated by other research," *id.*

b. *Nasal/Nasopharyngeal Cancer*

The Secretary's first reason for denying "positive association" between herbicide exposure and nasal cancer was that "[m]ost studies (e.g., [Kerstin Wiklund, *Swedish*

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[11] Marilyn A. Fingerhut, *et al., Cancer Mortality in Workers Exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin,* 324 New Eng. J. of Medicine 212 (1991) ("Fingerhut 1991, C.L. #1.24"); A. Manz, *et al., Cancer Mortality Among Workers in Chemical Plants Contaminated With Dioxin,* 338 Lancet 959 (1991) ("Manz 1991, C.L. #1.36"); Rodolfo Saracci, *et al., Cancer Mortality in Workers Exposed to Chlorophenoxy Herbicides and Chlorophenols,* 338 Lancet 1027 (1991) ("Saracci 1991, C.L. #1.47").

[12] Leon F. Burmeister, *Cancer Mortality in Iowa Farmers; 1971-1978,* 66 J. Nat'l Cancer Inst. 461 (1981) ("Burmeister 1978, C.L. #1.71"); Michael C.R. Alavanja, *et al., Mortality Among Forest and Soil Conservationists,* 44 Archives Envtl. Health 94 (1989).

Agricultural Workers: A Group With a Decreased Risk of Cancer, 51 Cancer 566 (1983) ("Wiklund 1983, C.L. #1.53"); Guglielmo Ronco, *et al., Cancer Risk Among Danish and Italian Farmers*, 49 British J. of Indus. Medicine 220 ("Ronco 1992, C.L. #1.46")]) showed inconclusive results, and often did not control for confounding variables." *Id.* at 345 (App. 43a). The only other reason the Secretary gave for denying positive association was that, even though three other studies (two of which the Secretary found were "based on the same three cases") "showed increased risk associated with herbicide exposure; . . . that risk was not statistically significant, which diminishes the importance of these studies." *Id.* at 345-46 (App. 43a).[13]

c. *Hepatobiliary Cancer*

With regard to hepatobiliary (liver and bile) cancer, the Secretary found:

> There are a variety of risk factors that should be considered by a credible study, including hepatitis B and C, alcohol abuse, cirrhosis, exposure to polychlorinated biphenyl (PCB), and smoking. The relevant studies are few, and have not adequately controlled for these risk factors. A Swedish case control study (Hardell L., [et al.], 1984. Aetiological aspects on primary liver cancer with special regard to alcohol, organic solvents and acute intermittent porphyria: an epidemiological investigation. British Journal of Cancer 50:389-397 [C.L. #1.28]) showed a relationship between herbicide exposure and the subsequent development of hepatobiliary cancer, however other studies of similar size [Ronco 1992, C.L. #1.46; Wiklund 1983, C.L. #1.53] indicated no

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[13] The three studies referred to by the Secretary were: David Coggon, *et al., Mortality of Workers Exposed to 2 methyl-4-chlorophenoxyacetic acid*, 12 Scandinavian J. of Work, Env't and Health 448 (1986) ("Coggon 1986, C.L. #1.21"); Saracci 1991, C.L. #1.47; and Lennart Hardell, *et al., Epidemiological Study of Nasal and Nasopharyngeal Cancer and Their Relation to Phenoxy Acid or Chlorophenol Exposure*, 3 Am. J. Indus. Med. 247 (1982) ("Hardell 1982, C.L. #1.27").

> relationship. A large occupational study (Fingerhut et al., 1991, [C.L. #1.24]) and a study of farmers in Denmark and Italy [the same Ronco 1992 study already relied on in the prior sentence] found no relationship. Accordingly, the Secretary has found that the credible evidence against an association between hepatobiliary cancer and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

Id. at 343 (App. 33a-34a).

5. Petitioners sought review in the Federal Circuit of the Secretary's rule denying a positive association and presumptive service connection as to the three diseases.[14]

With respect to prostate cancer, the court first set forth the Secretary's findings, most notably:

> There are statistically significant occupational studies which show no association between prostate cancer and herbicide exposure (e.g., Fingerhut . . .; Manz . . .; Saracci. . . .).

App. 20a (quoting 59 Fed. Reg. at 342). The court concluded that the Secretary:

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[14] As a threshold matter, the Federal Circuit determined, over the Secretary's objection, that the court had jurisdiction pursuant to 38 U.S.C. § 502, which provides that "[a]n action of the Secretary to which [5 U.S.C.] section 552(a)(1) . . . refers . . . is subject to judicial review. Such review shall be in accordance with [the Administrative Procedure Act] and may be sought only in the United States Court of Appeals for the Federal Circuit." App. 9a. Section 552(a)(1)(E) requires agencies to publish in the Federal Register, "substantive rules of general applicability . . . and statements of general policy or interpretations of general applicability . . . ." The court recognized that it "may directly review rules promulgated by the Department of Veteran's Affairs, including substantive rules of general applicability, statements of general policy and interpretations of general applicability." App. 9a-10a. The court concluded that the Secretary's determination was a "rule," and therefore subject to judicial review, because it was legislative and policy-making in nature in that it "prescribed the basis on which the Department would adjudicate every claim seeking disability or survivor benefits for specified diseases allegedly caused by exposure to herbicides in Vietnam." *Id.* at 10a.

> *erred* in citing the Fingerhut, Manz, and Saracci studies as supporting the statement that "[t]here are statistically significant occupational studies which show *no* association between prostate cancer and herbicide exposure." Instead, the three studies actually show a *positive* association, but are not statistically significant.

Id. at 21a (emphasis added). Nonetheless, the court upheld the Secretary's conclusion as to prostate cancer because "[i]t *would have* been accurately supported *if* the Secretary had cited to the Ronco and Wiklund studies, which were statistically significant and showed a negative association and none at all, respectively." *Id.* (emphasis added).

With respect to hepatobiliary cancer and nasal cancer, the court determined that the Secretary's finding of no positive association was not arbitrary and capricious. In so doing, the court rejected petitioners' contention that it was error on the part of the Secretary to fail to consider undisputed evidence of "biologic plausibility," *i.e.*, biological support for an association between exposure to dioxin, a contaminant contained in herbicides, and both hepatobiliary and nasal cancers. Jt. App. 211, 214. Although the court found that NAS "reported extensive evidence that dioxin caused cancer in laboratory animals," App. 20a, and that "the carcinogenicity of an herbicide contaminant [*e.g.*, dioxin] could be viewed as credible evidence of a positive association," *id.*, the court upheld the Secretary's failure to consider indisputably sound scientific evidence of biologic plausibility between dioxin and both hepatobiliary and nasal cancers because "the presence of dioxin in an herbicide does not compel the conclusion that there was such a relationship caused by exposure to the herbicide." *Id.*

REASONS FOR GRANTING THE PETITION

In *SEC* v. *Chenery Corp.*, 332 U.S. 194, 196 (1947) (*Chenery II*), this Court affirmed the fundamental principle of administrative law that "a reviewing court . . . must judge the propriety of [agency] action *solely* by the

grounds invoked by the agency." (Emphasis added). Adherence to this principle is necessary to ensure the proper separation of power between the judiciary and the administrative agencies of the Executive to which Congress has delegated exclusive authority to administer various statutory schemes. See *id.* The Federal Circuit's approach to review of agency decisions, as exemplified by its decision upholding the Secretary's denial of a positive association for prostate cancer based on evidence not relied on by the Secretary, undermines this critical balance.

The Federal Circuit has shown a willingness—in this and other cases—to depart from the *Chenery* doctrine by conducting its own review of the administrative record and substituting its judgment for that of the agency. The Federal Circuit's approach: (1) unduly intrudes into the domain of the political branches, (2) conflicts with the mandates of this Court, and (3) conflicts with the approaches employed in other circuits. A litigant seeking judicial review in the D.C. Circuit (as well as in other circuits) can expect the court to assess the propriety of the challenged agency action strictly on the bases relied upon by the agency. By contrast, a litigant traveling down the street and seeking judicial review in the Federal Circuit can now expect that court to substitute its own policy judgments where those rendered by the agency are unquestionably contrary to the evidence on which the agency relied.

This case is an especially good vehicle for clarifying the proper approach to judicial review of agency decisions. The substitution of the Federal Circuit's judgment for that of the agency is clear on the face of the court's opinion. In addition, given the strength of the evidence supporting a positive association for prostate cancer, the Secretary could well reach a different conclusion upon reconsideration. Furthermore, Congress's longstanding concerns—expressed in two legislative acts within the last decade—that veterans be compensated for harms associated with exposure to herbicides containing dioxin in

Vietnam, coupled with the Federal Circuit's exclusive jurisdiction over the Secretary's decision in this case, underscore the fact that this case raises important questions of federal law which should be settled by this Court.

With respect to hepatobiliary and nasal cancer, the Federal Circuit misconstrued the Agent Orange Act in permitting the Secretary to disregard evidence of the health effects of exposure to a contaminant contained in herbicides simply because the contaminant is not, in and of itself, an herbicide. This interpretation contravenes the Act's mandate to consider evidence of an association between "the exposure of humans to an *herbicide agent*" and "the occurrence of a disease in humans," 38 U.S.C. § 1116(b)(1) (emphasis added). The court's construction unduly restricts the type of evidence on which the Secretary is to base his determinations, contrary to the plain language of the Act. Were the Secretary to reconsider his determinations with reference to the previously ignored biological evidence in favor of association, again he might well find the statutory "positive association" standard met.

Both of the errors in the Federal Circuit's decision—the court's approach to judicial review and statutory interpretation—render untold numbers of Vietnam veterans without relief in frustration of Congress's policy of compensating those who have incurred harm in service of their country. Moreover, without proper guidance from this Court, the Secretary will likely *repeat* the errors left uncorrected by the Federal Circuit in the four or five future rounds of determinations required by the Agent Orange Act. See 38 U.S.C.A. § 1116 Note, sec. 3(g) (NAS to submit additional reports at least once every two years after first report); 38 U.S.C. § 1116(b)(2) (Secretary to make determinations based on the reports received from NAS under the Act); 38 U.S.C.A. § 1116(e) & Note, sec. 3(i) (Secretary's duty to make positive-association determinations shall cease ten years after year of first NAS report). For these reasons, this Court should review the decision of the Federal Circuit.

I.

1. "It is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983) (*"Motor Vehicle"*) (citations omitted). See also *SEC* v. *Chenery Corp.*, 318 U.S. 80, 93-94 (1943) (*"Chenery I"*) (An agency's "action must be measured by what the [agency] did, not by what it might have done."). As this Court explained in *Chenery II*:

> a reviewing court . . . must judge the propriety of [agency] action *solely* by the grounds invoked by the agency. If those grounds are inadequate or improper, *the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis.* To do so would propel the court into the domain which Congress has set aside exclusively for the administrative agency.

332 U.S. at 196 (emphasis added). Accordingly, no court is "empowered to substitute its judgment for that of the agency," *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 416 (1971) (*"Overton Park"*), but only to decide whether the agency's decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A). If the agency decision is "arbitrary and capricious,"[15] the court must vacate the decision and remand for further proceedings. See, *e.g.*, *Motor Vehicle*, 463 U.S. at 57; *Camp* v. *Pitts*, 411 U.S. 138, 143 (1973); *Chenery I*, 318 U.S. at 95.

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[15] An agency decision is "arbitrary, capricious [or] an abuse of discretion" under 5 U.S.C. § 706(2)(A) if any of the four following conditions is met: (1) the decision relies on factual determinations which are unsupported by, or contrary to, the record, *e.g.*, *Motor Vehicle*, 463 U.S. at 43, 52-53; (2) the decision fails to consider relevant factors, *e.g.*, *Overton Park*, 401 U.S. at 416; *Motor Vehicle*, 463 U.S. at 43; (3) the decision relies on irrelevant factors, *id.*; and/or (4) the agency's reasoning contains a "clear error of judgment," *e.g.*, *Overton Park*, 401 U.S. at 416; *Motor Vehicle*, 463 U.S. at 43.

The Secretary's decision denying a "positive association" between prostrate cancer and herbicide exposure is indisputably unsupported by the grounds on which *the Secretary* relied. The Secretary's entire assessment of whether the "credible evidence" in favor of association equals or outweighs the "credible evidence" against begins, and rests heavily on, his reliance on three specific studies, which purportedly demonstrate that "[t]here are statistically significant occupational studies which show no association between prostrate cancer and herbicide exposure." 59 Fed. Reg. 341, 342 (1994) (App. 31a). This critical finding is not only unsupported by, but contrary to, the very evidence cited by the Secretary. Those three studies —Fingerhut, Manz, and Saracci—stand for exactly the opposite principle from that for which the Secretary cites them: although not "statistically significant," they *do* show an association. Indeed, now the Secretary "concedes" this fact. See Secretary's Br. to Fed. Cir. at 36 (Oct. 14, 1994).

When that prop for the Secretary's analysis is knocked out, because it is contrary to the record, the assessment of the evidence is radically changed in the opposite direction. Now, instead of three statistically significant studies showing no association, as the Secretary improperly found, there are three credible studies all showing a *harmful* association, the very opposite of the Secretary's premise. Thus, at this first stage of the Secretary's analysis, what the record shows is three credible studies *in favor of* an association. Next, the Secretary acknowledges that other occupational studies show a "slight elevated risk for prostate cancer among farm and forestry workers." 59 Fed. Reg. at 342 (App. 31a). Then, the Secretary admits that there is one study, Morrison, which has *"associated the increased risk of prostate cancer among farmers specifically with herbicide exposure."* *Id.* (App. 31a-32a) (emphasis added). Thus, *all* the studies cited by the Secretary support an association for prostate cancer.

The Secretary's failure to cite a single study in support of his conclusion that the credible evidence "against" outweighed the credible evidence "for" an association, while citing several studies contrary to this conclusion, is a classic example of "arbitrariness" under the Administrative Procedure Act. See *Motor Vehicle*, 463 U.S. at 43 (explanation "counter to the evidence before the agency" is "arbitrary and capricious"); accord *St. James Hosp.* v. *Heckler*, 760 F.2d 1460, 1468 (7th Cir.) (reliance on study "seriously undermin[ing]" agency's conclusions as sole factual basis for rule is "clear error of judgment"), *cert. denied*, 474 U.S. 902 (1985); see also *Weyerhauser Co.* v. *Costle*, 590 F.2d 1011, 1029-31 & n.22 (D.C. Cir. 1978). Nor is this harmless error. Since a court "cannot be sure that under the correct [facts the Secretary] would have reached the same conclusion, [it] cannot characterize the defect as harmless." *Id.* at 1031 n.27.

On review, the Federal Circuit recognized the error in the Secretary's interpretation of the evidence when it expressly found that the Secretary:

> *erred* in citing the Fingerhut, Manz, and Saracci studies as supporting the statement that "[t]here are statistically significant occupational studies which *show no association* between prostate cancer and herbicide exposure." Instead, the three studies *actually show a positive association*, but are not statistically significant.

App. 21a (emphasis added). Thus, it is undisputed that the Secretary "offered an explanation for [his] decision that runs counter to the evidence before the agency." *Motor Vehicle*, 463 U.S. at 43. Such action is "[n]ormally . . . arbitrary and capricious." *Id.* That should have ended the court's analysis and justified a remand to the Secretary.

However, the Federal Circuit sought to cure the Secretary's erroneous reliance on the three specific studies by searching the record on its own to find two other studies—which the Secretary never cited—to support his "finding"

of statistically significant studies showing no association. The court reasoned that the Secretary's finding "*would have* been accurately supported *if* [he] had cited to the Ronco and Wicklund studies." App. 21a. On its face, the court's substituting other studies for the ones the Secretary actually relied on runs afoul of the fundamental principle that "an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Vehicle*, 463 U.S. at 50. Since the agency has "offered an explanation for its decision that runs counter to the evidence before [it] . . . [t]he reviewing court [may] not attempt itself to make up for such deficiencies." *Id.* at 43.

The Federal Circuit could not properly speculate how the Secretary would have decided "positive association" for prostate cancer if he had known that all of the three studies he misread as showing "no association" in fact showed the very opposite: a "positive association." The Agent Orange Act places responsibility, in the first and last instance, with *the Secretary* to weigh the evidence and determine whether a positive association exists. See 38 U.S.C. § 1116(b)(1) ("Whenever *the Secretary* determines, on the basis of sound medical and scientific evidence, that a positive association exists . . .") (emphasis added); *id.* § 1116(b)(2) ("In making determinations . . ., *the Secretary* shall take into account (A) [NAS] reports . . . and (B) all other sound medical and scientific information and analyses available to *the Secretary*. In evaluating any study . . ., *the Secretary* shall take into consideration" factors bearing on the weight to be given the study) (emphasis added). The Secretary himself concedes and explains at length that it is *his* duty to *weigh* the evidence to determine whether there is a "positive association" for any disease. See 59 Fed. Reg. at 342 (App. 29a). Thus, only the Secretary is properly situated to reconsider his decision in light of the erroneousness of the factual premises for his previous decision. Under the precedents of this Court, the Secretary's decision on prostate cancer should be vacated and the case remanded to the Secretary for further consideration. See,

e.g., *Motor Vehicle*, 463 U.S. at 57; *Camp* v. *Pitts*, 411 U.S. 138, 143 (1973); *Chenery I*, 318 U.S. at 95.

2. The Federal Circuit's willingness to substitute its judgment for that of an agency has revealed itself in other cases as well. In *Ward* v. *Merit Systems Protection Board*, 981 F.2d 521 (Fed. Cir. 1992), the Federal Circuit expressly acknowledged that it was upholding an agency's decision under a different theory than that applied by the agency. The court distinguished *Chenery I* stating that, notwithstanding *Chenery I*'s "broad statements with respect to the basis of judicial review of an administrative decision," the case only requires that agency actions not be upheld on "*entirely* different" grounds. *Ward*, 981 F.2d at 527 (emphasis added). The theory applied by the court in *Ward*, although different from the agency's, the court reasoned, was permissible because it was not "wholly different" and it was clear that the agency would have reached the same conclusion under the court's new theory.

The *Ward* court's reasoning was flawed. First, the *Chenery* doctrine does not only preclude courts from affirming agency actions on "wholly" or "entirely" different grounds, it precludes affirmance on *any* basis if the agency's action, viewed *solely* on the grounds articulated by the agency, is improper. See *Chenery II*, 332 U.S. at 196; accord *Motor Vehicle*, 463 U.S. at 43, 50. The court's attempt to justify upholding the agency's decision because the court believed the agency would reach the same conclusion is precisely the type of second-guessing the *Chenery* doctrine prohibits. Indeed, the risk inherent in predicting what the agency *would have* done had it applied a proper basis for its action is aptly illustrated by the *Ward* decision. Contrary to the court's reasoning, it is far from clear that the agency would have reached the same conclusion under the theory supplied by the court.[16]

[16] The Merit Systems Protection Board had determined that a federal employee was not covered by the Whistleblower Protection Act for complaining about the travel expenses of another employee on the ground that the travel expenses of a single individual simply

Even more remarkable, in *Sealed Air Corp.* v. *United States ITC*, 645 F.2d 976 (C.C.P.A. 1981), the Federal Circuit's predecessor [17] purported to be *required* by *Chenery I* to *uphold* an agency's decision that the court found was based on a "mistaken" belief. According to the court, "[an agency's] decision must be affirmed where the result is correct, notwithstanding its reliance on a wrong ground or a wrong reason." *Id.* at 986 (citing *Chenery I*, 318 U.S. at 88). The court fundamentally misread this Court's discussion in *Chenery I*.

After reiterating the principle that "[t]he grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based," *Chenery I*, 318 U.S. at 87, the Court observed:

> In confining our review to a judgment upon the validity of the grounds upon which the Commission itself based its action, we do not disturb the settled rule that, in reviewing the decision of a lower *court*, it must be affirmed if the result is correct "although

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cannot constitute "a gross waste of funds." *Ward* v. *Merit Sys. Protection Bd.*, 981 F.2d 521, 527 (Fed. Cir. 1992). The court disagreed, concluding that one person's travel expenses may amount to a gross waste of funds under certain circumstances. *Id.* at 528. The court upheld the agency action, however, because on the facts of the case, in the court's opinion, the travel expenses did not reach that level. The court reasoned that since it was purportedly applying to the particular facts a "narrower" formulation of the same "general rules" applied by the agency, it was clear that the agency would have reached the same conclusion under the court's theory. *Id.* at 527-28.

This reasoning is illogical. The agency denied relief because it was laboring under the mistaken belief that, *as a rule*, travel expenses by one individual can never constitute a gross waste of funds. If, however, the agency understood that the question called for a particularized factual determination, it might have found that a gross waste of funds had occurred.

[17] The United States Court of Customs and Patent Appeals preceded the creation of the Federal Circuit and its decisions, rendered prior to and including September 30, 1982, are binding precedent in the Federal Circuit. *See South Corp.* v. *United States*, 690 F.2d 1368, 1369-70 (Fed. Cir. 1982) (*en banc*).

> the lower court relied upon a wrong ground or gave a wrong reason."

Id. at 88 (quoting *Helvering* v. *Gowran*, 302 U.S. 238, 245 (1937)) (emphasis added). The Court in *Chenery I* was merely explaining that the proscription against a court's substituting its judgment for that of an *administrative agency* is different from the equally well-settled principle that a reviewing court should affirm a *judicial* decision if sustainable on any legal theory. Accordingly, as the dissent in *Sealed Air Corp.* recognized, "[*Chenery I*], relied upon by the majority, *prohibits rather than endorses* the substitution of the court's findings to sustain the [International Trade Commission's] order below." 645 F.2d at 990 (Nies, J., dissenting) (emphasis added); see also *id.* at 997 ("No support can be found in *Chenery* [*I*] or *Helvering* for this court to uphold an order by interjecting a new ground, *sua sponte* . . . .").

Thus, the decision by the Federal Circuit in the instant case is not an aberration; instead it represents the Federal Circuit's practice of upholding agency decisions on grounds not relied on by the agency. Through its approach of "affirm[ing] the administrative action by substituting what it considers to be a more adequate or proper basis," the Federal Circuit has wrongfully "propel[led] the court into the domain which Congress has set aside exclusively for the administrative agency." *Chenery II*, 332 U.S. at 196. Accordingly, the Court should grant this petition.

3. Not only does the Federal Circuit's approach to reviewing agency actions flout this Court's precedent, it creates an intolerable conflict between the Federal Circuit and other circuits. When agency decisions are reviewed in these other circuits, agencies are entitled to reconsider their rules if initial decisions were erroneous. For example, in *Asarco, Inc.* v. *United States EPA*, 616 F.2d 1153 (9th Cir. 1980), the Ninth Circuit vacated an order by the Environmental Protection Agency because it could not be supported by the grounds relied on by the

agency. In so doing, the court criticized the trial court for conducting a *de novo* review of the evidence relating to the agency's action:

> Consideration of the evidence to determine the correctness or wisdom of the agency's decision is not permitted, even if the court has also examined the administrative record. If the court determines that the agency's course of inquiry was insufficient or inadequate, it should remand the matter to the agency for further consideration and not compensate for the agency's dereliction by undertaking its own inquiry into the merits.

Id. at 1160.[18]

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[18] *Accord Cincinnati Bell Tel. Co.* v. *FCC*, 69 F.3d 752, 758 (6th Cir. 1995) (finding agency rule unsupported by agency's reasons and requiring remand for agency to reconsider since "[w]e will not supply the basis for the agency's action, but instead rely on the reasons advanced by the agency in support of the action") (citations omitted); *OXY USA, Inc.* v. *FERC*, 64 F.3d 679, 693-94 (D.C. Cir. 1995) (noting that alternative reason might support agency's order, but remanding because "[i]t is not the reason that the Commission adopted, however, and we may affirm the agency only on the grounds upon which it relied in exercising its power") (citations omitted); *Madison Gas & Elec. Co.* v. *United States EPA*, 25 F.3d 526, 528 (7th Cir. 1994) (refusing to uphold agency order on alternative basis proposed by agency's lawyer stating that "[w]hether that is a good or a bad ground for the agency's decision . . ., it is not a ground that the agency articulated. We are therefore barred by the *Chenery* doctrine from upholding its decision on the basis of it.") (citations omitted); *Puerto Rico Sun Oil Co.* v. *United States EPA*, 8 F.3d 73, 79 (1st Cir. 1993) (vacating agency's order notwithstanding that rationale might exist to support agency's action since an "agency's decision cannot be supported on reasoning that the agency has not yet adopted") (citations omitted); *Facchiano Constr. Co.* v. *United States Dep't of Labor*, 987 F.2d 206, 215 (3d Cir.) (directing remand to agency because basis articulated by agency did not support agency's action), *cert. denied*, 114 S. Ct. 80 (1993); *Mayo* v. *Schiltgen*, 921 F.2d 177, 179 (8th Cir. 1990) (reversing district court's affirmance of agency decision on new ground because "a reviewing court cannot search the record to find other grounds to support the [agency's] decision"); *Pennzoil Co.* v. *FERC*, 789 F.2d 1128, 1136 & n.21 (5th Cir. 1986) (vacating and remanding

In the Federal Circuit, in contrast, if an agency makes critical mistakes in formulating rules, the court will usurp the agency's discretion and decide for itself whether the agency's rules should be upheld on alternative grounds. In addition to veterans benefits claims, the Federal Circuit has exclusive jurisdiction to review cases from a number of administrative agencies in a variety of substantive areas including military discharge claims; import regulations; civil service disputes, and patent cases.[19] Accordingly, the flawed approach employed in the Federal Circuit here adversely affects not only the litigants in this particular dispute, but litigants nationwide involved in a wide range of cases falling within the Federal Circuit's jurisdiction.

Absent an expressed intent by Congress, which has not been made, the Federal Circuit does not have greater discretion in reviewing decisions by agencies within its jurisdiction than the other federal courts have over agency actions brought within theirs. Such a conflict in judicial review is intolerable and should be corrected by this Court.

4. This case presents an especially compelling case for this Court to clarify the proper role of the judiciary in reviewing agency action.

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agency order because agency failed to give proper weight to credibility findings of Administrative Law Judge, and agency's decision may be upheld only "on the ground upon which the agency acted") (citations omitted); *Action, Inc.* v. *Donovan*, 789 F.2d 1453, 1457 (10th Cir. 1986) (refusing to uphold agency decision where agency failed to give adequate reasons and stating that "[a]lthough there may be grounds for [agency's decision], this court cannot attribute to the Secretary appropriate reasons for his decision").

[19] Areas of jurisdiction assigned to the Federal Circuit include appeals from: the Patent and Trademark Office, 28 U.S.C. § 1295(a)(4); the United States International Trade Commission, 28 U.S.C. § 1295(a)(6); certain findings of the Secretary of Commerce, 28 U.S.C. § 1295(a)(7); the Merit Systems Protection Board in disputes under the civil service law, 28 U.S.C. § 1295(a)(9); and certain rule-making by the Secretary of Veterans Affairs, 38 U.S.C. § 502.

First, it is beyond dispute that the court below upheld the agency's rule on bases not relied on by the agency. As demonstrated above, see *supra* pp. 8-9, 16-17, central to the Secretary's determination that the evidence in the administrative record against an association between prostate cancer and herbicide exposure outweighs the evidence supporting an association is the Secretary's finding that "[t]here are statistically significant occupational studies which show no association between prostate cancer and herbicide exposure." 59 Fed. Reg. 341, 342 (1994) (App. 31a). It is undisputed that the only studies cited in support of this finding in fact *do* show an association. Furthermore, it is clear that the Federal Circuit recognized that, without those studies, the grounds articulated by the Secretary did not support his finding, concluding that the finding "would have" been supported only "if" he had referred to studies he had not mentioned. App. 21a. Thus, the court's opinion starkly illustrates that the court upheld the Secretary's determination concerning prostate cancer on bases not relied on by the Secretary and without which the court knew the Secretary's finding lacked a foundation.

Second, the evidence supporting a positive association for prostate cancer is sufficiently weighty that a remand for reconsideration would not be a useless formality but reasonably could result in a different outcome now that the Secretary is aware of the true relevance of the studies he relied on previously. The NAS Report, on which the Secretary principally relied, placed prostate cancer in the second highest category of diseases for which evidence supported an association with herbicide exposure—"Limited/Suggestive Evidence of an Association." See *supra* note 9. Prostate cancer is the *only* disease among the three diseases placed in this category and the five placed in the highest category, Jt. App. 106F, 106G, for which the Secretary did not find a positive association, and accordingly, did not grant presumptive service connection. See 55 Fed. Reg. 43,123, 43,124 (1990) (NHL); 56 Fed. Reg. 51,651 (1991) (STS); 56 Fed. Reg. 29,719,

29,723 (1991). Since NAS found the evidence "suggestive" of an association, and the standard for finding a positive association requires only that the evidence in favor be at least "equal to" the evidence against an association, 38 U.S.C. § 1116(b)(3), the Secretary might well find such an association for prostate cancer, as he did for other "suggestive" diseases, now that his previous misinterpretation of the three studies has been corrected. Indeed, since the Secretary presumably cited only those studies he found significant, and *all* the cited studies concerning prostate cancer support an association with exposure to herbicide agents, it seems inconceivable that the Secretary would not find a positive association upon reconsideration.

Third, policy concerns underlying the Agent Orange Act and its broad impact on a whole class of veterans demand that the Act be administered according to the scheme devised by Congress. As discussed above, see *supra* pp. 3-7, the Agent Orange Act represents a continuing effort by Congress to ensure compensation to veterans exposed to herbicides containing dioxin during their service in the Vietnam War. That war and the ensuing controversy over the effects of Agent Orange have divided this country like few other issues. Resolving an issue of such controversial and public concern calls for the exercise of political judgment and policy-making discretion. Congress has made that judgment in the Agent Orange Act and enlisted the expertise of the Secretary to carry out Congress's objectives. The Secretary's decision affects not only the petitioners here but all veterans who have suffered from diseases potentially associated with exposure to herbicide agents used in support of military operations in Vietnam. See 1 Kenneth C. Davis, *Administrative Law Treatise* § 5.01 (1958).

Finally, without this Court's intervention, the Secretary's denial of presumptive service connection effectively precludes Vietnam veterans with prostate cancer from seeking relief *of any kind*. Because veterans or spouses affected by prostate cancer cannot gain benefits on the

basis of presumptive service connection, they cannot, as a practical matter, gain any benefits on any basis.[20]

Moreover, since the Federal Circuit is the only circuit with jurisdiction to review the Secretary's rule, see 38 U.S.C. § 502, that court's determination binds all veterans nationwide. This Court has recognized that, due to the Federal Circuit's exclusive jurisdiction over cetrain subject matters, its decisions are "a matter of special importance to the entire Nation" justifying review by this Court. See *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 113 S. Ct. 1967, 1971 (1993).

Furthermore, due to considerations of sovereign immunity and in light of the alternative administrative scheme created by Congress for compensating veterans, as illustrated by the Agent Orange Act, veterans are precluded from pursuing tort actions against the government for their herbicide agent-related injuries. See *Stencel Aero Eng'g Corp.* v. *United States*, 431 U.S. 666, 672-73 (1977); *Feres* v. *United States*, 340 U.S. 135, 144 (1950). Given the policy concerns underlying the Agent

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[20] The Secretary argued in the Federal Circuit, Secretary's Br. at 22, that his denial of positive association does not preclude eligibility for benefits because, in theory, an individual can attempt to prove that his disease was incurred as a result of military service. *See* 38 U.S.C. § 1113(b); 38 C.F.R. § 3.303(d). The court properly rejected this argument, observing that in enacting the scheme for establishing presumptions, Congress recognized the virtual impossibility of establishing, in an individual case, that a veteran's disease is service connected. *See* App. 11a. This recognition is what led Congress to enact the Veterans' Dioxin and Radiation Exposure Compensation Standards Act of 1984 and, subsequently, the Agent Orange Act of 1991. *See, e.g.*, 130 Cong. Rec. S6156-57 (daily ed. May 22, 1984) (statement of Sen. Simpson) ("[it] is impossible . . . to make any absolute determination as to cause and effect."); *see also* 130 Cong. Rec. S6152 (daily ed. May 22, 1984) (statement of Sen. Specter); *Combee* v. *Brown*, 34 F.3d 1039, 1041-42 (Fed. Cir. 1994) (discussing difficulty of proving direct service connection for radiation exposure). Indeed, petitioners are aware of no case in which direct service connection has been granted based on exposure to herbicides, and the Secretary has cited none.

Orange Act and its exclusivity as a remedy for herbicide agent-injured veterans, it is crucial that the proper decision-maker—the Secretary—be given the opportunity to perform his function within the administrative scheme devised by Congress.

II.

The Federal Circuit's decision concerning hepatobiliary cancer and nasal cancer is also erroneous and indepedently justifies review by this Court. The Federal Circuit acknowledged that NAS "reported extensive evidence that dioxin caused cancer in laboratory animals." App. 20a. Further, the court noted that "the carcinogenicity of an herbicide contaminant [*e.g.*, dioxin] could be viewed as credible evidence of a positive association." *Id.* However, the court held, in effect, that the Secretary could ignore indisputably sound scientific evidence of a biologically plausible link between dioxin and both hepatobiliary and nasal cancers because dioxin is not, in and of itself, an herbicide: "the presence of dioxin in an herbicide does not compel the conclusion that there was such a relationship caused by exposure to the herbicide." *Id.*

The premise for the court's rulng appears to have been that in making "positive association" determinations under the Agent Orange Act, the Secretary was only legally obligated to consider sound scientific evidence of association between "herbicide exposure" and disease, *not* such evidence of association between an "herbicide contaminant," *i.e.*, dioxin, and disease. Since the NAS Report established "biologic plausibility" only between dioxin and the two cancers, and that did not necessarily imply plausibility between "herbicide exposure" and disease, the court reasoned, the Secretary had no legal duty to consider biologic plausibility as to dioxin.

The court's premise is wrong as a matter of law. The Act's plain language establishes that the evidence the Secretary must consider in making determinations as to "positive association" is exactly what the court permitted the Secretary to ignore. The Secretary must determine whether "a positive association exists between (A) *the*

exposure of humans to an *herbicide agent,* and (B) the occurrence of a disease in humans. . . ." App. 4a (quoting 38 U.S.C. § 1116(b)(1)) (emphasis added). "Herbicide agent" is statutorily defined as "a chemical in an herbicide used in support of the United States and allied military operations in the Republic of Vietnam during the Vietnam era." 38 U.S.C. § 1116(a)(4). Thus, dioxin is indisputably an "herbicide agent."

In short, the statute expressly mandates the Secretary to consider "sound medical and scientific evidence" of a positive association between exposure to an "herbicide agent" (here, dioxin) and "a disease in humans." *Id.* § 1116(b)(1). It is undisputed that the evidence of biologic plausibility between dioxin exposure and both hepatobiliary and nasal cancers is "sound . . . scientific evidence." Further, it is unchallenged that the evidence of biologic plausibility is evidence supporting a positive association between "exposure of humans to an herbicide agent, and . . . disease in humans" under 38 U.S.C. § 1116(b)(1). See NAS Report at 5-16, 5-18 (Jt. App. 197, 199); 38 U.S.C.A. § 1116 Note, sec. 3(d)(1)(C). And it is beyond cavil that the Secretary, in making determinations as to positive associations, must "take into account" not only the NAS's reports but "all other sound medical and scientific information and analyses available to the Secretary," 38 U.S.C. § 1116(b)(2).

Thus, by permitting the Secretary to disregard available and highly material evidence of biologic plausibility between dioxin exposure and the two diseases, the court's decision violates the plain language of § 1116(b)(2). See *Brown* v. *Gardner,* 115 S. Ct. 552, 557 (1994) (courts owe no deference to agency's interpretation of statute when it "flies against the plain language of the statutory text"); *Dole* v. *United Steelworkers of Am.,* 494 U.S. 26, 42-43 (declining to defer to agency interpretation where statute clearly expressed congressional intent), *cert. denied sub nom. Associated Builders & Con-*

tractors, Inc. v. *OSHA*, 494 U.S. 1003 (1990); *Board of Governors of Fed. Reserve Sys.* v. *Dimension Fin. Corp.*, 474 U.S. 361, 368 (1986) ("The traditional deference courts pay to agency interpretation is not to be applied to alter the clearly expressed intent of Congress."); *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984) ("If the intent of Congress is clear, that is the end of the matter.").

This violation is highly prejudicial because the evidence might very well have caused the Secretary to decide that there is a "positive association" between the two diseases and exposure to "an herbicide agent." The Secretary's failure to consider biologic plausibility made the Secretary's denial of positive association for hepatobiliary and nasal cancers "arbitrary, capricious, . . . [and] otherwise not in accordance with the law," 5 U.S.C. § 706 (2)(A), and the court erred by upholding that denial.

Nor is this conclusion undermined by the Federal Circuit's observation that Congress did not explicitly require the Secretary to consider evidence of biologic plausibility in making "positive association" determinations. App. 19a. The absence of an explicit mandate does not imply that the Secretary was not required to consider such evidence. Congress likewise failed to mention expressly any requirement that the Secretary consider epidemiological evidence in making those determinations, yet no one could suggest that the Secretary is, because of the absence of such language, free to disregard epidemiological studies in making his "positive association" determinations. Congress plainly did not authorize the Secretary to turn a blind eye to *any* of the relevant scientific evidence in making his "positive association" determination.

There was no need for Congress to list the specific types of scientific evidence the Secretary had to consider because Congress gave him a more general directive: he must consider the NAS's "reports" and "all other sound . . . scientific information and analyses available to [him]," 38 U.S.C. § 1116(b)(2), relevant to whether

there is an association between exposure to an "herbicide agent" and "a disease in humans," *id.* § 1116(b)(1). As applied here, that broader legal mandate necessarily requires the Secretary to consider both evidence of "biologic plausibility" (from toxicological studies) and evidence from epidemiological studies because both provide "sound scientific evidence" of positive association between exposure to the herbicide agent dioxin and the two diseases at issue.

The court's erroneous endorsement of the Secretary's statutory construction essentially guts the mandate of the Agent Orange Act to base determinations of positive association on *all* relevant available evidence. If allowed to stand, the court's ruling will seriously undermine the Act's effectiveness.

As a practical matter, the court's ruling denies relief to all Vietnam veterans or spouses affected by hepatobiliary and nasal cancer. By sanctioning the Secretary's decision to disregard relevant and credible evidence of the harmful effects of herbicide agents such as dioxin, the court has rendered unfairly difficult, if not futile, any attempts to challenge any of the Secretary's denials of positive association. In so doing, the Federal Circuit has frustrated Congress's policy judgments embodied in the Agent Orange Act that veterans are entitled to VA compensation for a particular disease if the scientific evidence in favor of an association between the disease and exposure to an herbicide agent is not outweighed by the evidence against. This error warrants review by this Court.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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February 12, 1996

APPENDICES

APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

94-7050

JENNIE R. LEFEVRE, SALLY M. HILL,
FREDERICK L. RADA AND MARY CHRISTINA VELDMAN,
Petitioner,

v.

SECRETARY, DEPARTMENT OF VETERANS AFFAIRS,
Respondent.

DECIDED: September 15, 1995

Before RICH, *Circuit Judge,* FRIEDMAN, *Senior Circuit Judge,* and MICHEL, *Circuit Judge.*

FRIEDMAN, *Senior Circuit Judge.*

The issue on the merits is the validity of the determination of the Secretary of Veterans Affairs, pursuant to the Agent Orange Act of 1991, 38 U.S.C. § 1116 (Supp. V. 1993 (the 1991 Act), not to create a presumption that prostate cancer, liver cancer, and nose cancer are connected to exposure to herbicides in Vietnam, which would be applied in determining eligibility for disability and survivor's benefits. The Secretary contends that under the 1991 Act we do not have jurisdiction to review his determination. We hold that we have jurisdiction, and affirm his determination.

I.

A. In 1984, Congress recognized that it would be virtually impossible to determine on a case-by-case basis

whether exposure to herbicides in Vietnam caused a disease in a particular veteran. 130 Cong. Rec. 13,159 (remarks of Senator Simpson). It therefore decided to require the Secretary to create a reject a presumption-of-service connection for particular diseases, based upon the statistical probability of such connection, as reflected in scientific studies of the relationship between those diseases and exposure to herbicides and the incidence of those diseases in persons and animals subject to herbicide exposure. *Id.* at 13,157-59; *See* Veterans' Dioxin and Radiation Exposure Compensation Act of 1984, Pub. L. No. 98-542, 98 Stat. 2725 (1984 Act).

By 1991 Congress had concluded that the Secretary's administration of the 1984 Act had created doubt about the way the Act was being applied. A Senate Committee report on the 1991 Act stated:

> A number of reviews of the scientific literature on the effects of exposure to dioxin have been carried out under contract with VA and published by VA pursuant to the mandate in [the 1984 Act]. . . . General acceptance of these reviews has been impaired because of concern that VA may have exerted influence on their content. Although the Committee does not share such a concern, it nevertheless recognizes that the perception of a possibility of some taint does exist and cannot be dismissed out of hand. Other than these reviews, the Committee is unaware of any other unified analysis of the results obtained from studies on the effects of dioxin exposure or of any up-to-date analysis.

S. Rep. No. 101-82, 101st Cong., 1st Sess. 41 (1989).

Congress therefore enacted the 1991 Act to provide

> a review, by an entity completely independent of VA, that will yield unified compilation and analysis of the results from the various scientific studies.

> In order to accomplish this result, the Committee bill would provide for an independent contract scientific organization—the National Academy of Sciences unless NAS is unwilling to undertake this effort—to undertake a comprehensive review and evaluation of all of the scientific evidence, literature, and studies —including the Selected Cancers (SC) Study being carried out by CDC—pertaining to the adverse health effects in humans or other animals of exposure to dioxin and other substances in herbicides used in Vietnam.

Id. at 42.

The 1991 Act directed the Secretary to seek to enter into an agreement with the National Academy of Science (the Academy or NAS), an independent non-profit, non-governmental scientific organization, under which the Academy would "review and summarize the scientific evidence and assess the strength thereof, concerning the association between exposure to an herbicide used in support of military operations in Vietnam," and "each disease suspected to be associated with such exposure." 38 U.S.C. § 1116, Note, § 3(c). The agreement was to require the Academy to transmit to the Secretary written reports over ten years, the first within 18 months and the remaining ones at least every two years. *Id.*, Note § 3(g)(i).

Under the 1991 Act the Academy is directed, "[f]or each disease reviewed," to

> determine (to the extent that available scientific data permit meaningful determinations)—
>
> (A) whether a statistical association with herbicide exposure exists, taking into account the strength of the scientific evidence and the appropriateness of the statistical and epidemiological methods used to detect the association;

> (B) the increased risk of the disease among those exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and
>
> (C) whether there exists a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the disease.
>
> (2) the Academy shall include in its reports under subsection (g) a full discussion of the scientific evidence and reasoning that led to its conclusions under this subsection.

Id., Note § 3(d).

Within 60 days of receiving the Academy's report, the Secretary is to determine whether a "positive association existed between (A) the exposure of humans to an herbicide agent, and (B) the occurrence of a disease in humans . . . ." 38 U.S.C. § 1116(b)(1). There is such a positive association "if the credible evidence for the association is equal to or outweighs the credible evidence against the association." 38 U.S.C. § 1116(b)(3). If the Secretary determines, "on the basis of sound medical and scientific evidence," that such positive association exists, he is required to establish a presumption of service connection for the disease. 38 U.S.C. § 1116(b)(1).

In making his determinations, the Secretary is required to "take into account" the Academy's report and "all other sound medical and scientific information and analysis available to the Secretary." 38 U.S.C. § 1116(b)(2). "In evaluating any study for the purpose of making such determinations, the Secretary shall take into consideration whether the results are statistically significant, are capable of replication, and withstand peer review." *Id.*

B. Pursuant to its agreement with the Secretary, the Academy conducted an extensive investigation in which it "review[ed] and summarize[d] the strength of the scientific evidence concerning the association between herbicide exposure during Vietnam service and each disease or con-

dition suspected to be associated with such exposure." The result was a 764 page Report, which exhaustively reviewed the scientific evidence regarding the association between exposure to herbicides and various diseases. The Academy made no new studies, but reviewed existing evidence including various epidemiological studies and studies of biologic plausibility. The latter is biological evidence, usually from animal testing, that a particular agent is associated with a particular disease. The Report was based on the Academy's review of more than 6000 abstracts of scientific or medical articles, approximately 230 of which were given detailed analysis.

The Academy summarized the extent of the evidence of association between herbicide exposure and 31 specific health problems by placing each disease in one of four categories. The first category, diseases for which the scientific evidence constituted "Sufficient Evidence of an Association" "Between Specific Health Problems and Exposure to Herbicides," contained five diseases, none of which is at issue in this case. The second category was:

> Limited/Suggestive Evidence of an Association: Evidence is suggestive of an association between herbicides and the outcome but is limited because chance, bias, and confounding could not be ruled out with confidence. For example, at least one high-quality study shows a positive association, but the results of other studies are inconsistent.

The Report placed three types of cancer in this category, one of which, prostate cancer, is at issue here.

The third category was:

> Inadequate/Insufficient Evidence to Determine Whether an Association Exists: The available studies are insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association. For example, studies fail to control for confounding, have inadequate exposure assessment, or fail to address latency.

The Report placed 20 diseases in this category. Two of them—hepatobiliary (liver) and nasal/nasopharyngeal (nose) cancer—are at issue here.

The fourth category, "Limited/Suggested Evidence of No Association," contains 4 types of cancer. None of these is here involved.

The Report noted that the Academy "was charged with reviewing the scientific evidence, rather than making recommendations regarding DVA policy, and [placement of the diseases in categories] is not intended to imply or suggest any policy decisions, which must rest with the Secretary."

The Report also considered separately whether exposure to herbicides increased risk for Vietnam veterans for each of the diseases. It concluded that "it is not possible for the Academy to quantify the degree of risk likely to have been experienced by Vietnam veterans because of their exposure to herbicides in Vietnam," "giv[en] the large uncertainties that remain about the magnitude of potential risk from exposure to herbicides in the occupational, environmental and veterans studies that have been reviewed, inadequate control for important confounders in these studies, and the lack of information needed to extrapolate from the level of exposure in the studies reviewed to that of individual Vietnam veterans . . . ." *Id.*

In assessing the evidence of biologic plausibility, the Report noted: "Several studies . . . have been performed in laboratory animals. In general they have produced negative results, although some were not performed using rigorous criteria for the study of cancer in animals, and some produced equivocal results that could be interpreted as either positive or negative. . . . [T]here is as yet no convincing evidence of, or mechanistic basis for, the carcinogenicity of any of the herbicides used in Vietnam." The Report also addressed the chemical compound known as TCDD or dioxin, which was a contaminant "found in varying levels in different batches of Agents Orange,

Pink, Purple, and Green." The Academy reported that there was extensive evidence that dioxin caused cancer in laboratory animals.

C. Upon receipt of the Academy's Report, the Secretary announced that he would recognize as service connected the five diseases the Report had placed in the first category ("Sufficient Evidence of an Association"). The Department appointed a task force, "an internal, high-level panel" of experts, "to carefully analyze the report from a medical/scientific perspective and to solicit comments from representatives of veterans service organizations and other interested parties."

In a detailed report to the Secretary, the task force "attempt[ed] to translate the Academy's evaluation of the scientific literature and other available information into terms compatible with the legal mandate of P.L. 102-4, i.e. whether the credible evidence for an association between exposure to herbicides and any specific disease was equal to or outweighed the credible evidence against an association. This is not a simple task. The Task Force also tried to evaluate additional evidence presented by the veterans service organizations and a recently published follow-up on the Seveso incident published in *Epidemiology*." The task force concluded that the Academy "had done a thorough review and evaluation of the available scientific and medical information regarding health effects of the exposure to Agent Orange and other herbicides used during the Vietnam conflict. There were no obvious gaps in the information sources cited," and "the approach taken by the NAS Committee was reasonable and scientifically sound and the organization of the report was understandable."

The task force made recommendations based on the Academy's conclusions. It endorsed the Secretary's decision that the five diseases that the Academy placed in its first category ("Sufficient Evidence of an Association")

"also meet the standard for a positive finding under the statute, i.e., the credible evidence for an association is equal to or outweighs the credible evidence against an association." The task force spent substantial time on the three types of cancer that the Academy placed in the second category ("Limited Suggestive Evidence of an Association"). The task force concluded that two of those cancers (respiratory cancers and multiple myeloma) met the statutory standard and recommended the establishment of a presumption of service connection for them. It concluded, however, that prostate cancer did not meet the statutory standard and recommended not establishing a presumption of service connection for it. The task force concluded that none of the diseases that the Academy placed in the third category ("Inadequate/Insufficient Evidence of an Association"), which included liver and nose cancer, met the statutory standard, and recommended not to establish a presumption of service connection for them.

The Secretary adopted the task force's recommendations, and published a detailed explanation of his decision in the Federal Register. 59 Fed. Reg. 341-46 (1994). He explained his reasons for denying a presumption of service connection for most of the diseases, including the three here at issue. The Secretary discussed the scientific reports, both pro and con, upon which he based his decision. The Secretary requested that the Academy "focus particularly on the evidence regarding prostate cancer and peripheral neuropathy in its next review."

D. The four petitioners are a Vietnam veteran who has prostate cancer and three widows of Vietnam veterans who died of liver or nose cancer. They allege that the veterans' exposure to herbicides in Vietnam caused the cancers. The veteran has a claim for disability compensation pending before the Department of Veterans Affairs. The three widows have pending their claims for dependency and indemnity compensation. The petition for re-

view asserts that the Secretary's denial of a presumption for the three types of cancer "will cause the VA imminently to deny their claims for compensation."

The petition for review challenges the Secretary's determination "insofar as it determines *not* to allow veterans presumptive service connection, based on herbicide exposure in Vietnam, for prostate cancer, hepatobiliary cancers and nasal/nasopharyngeal cancer" (emphasis in original). The petitioners' brief asserts that the Secretary's denial of a "positive association" between those three types of cancers and exposure to herbicides in Vietnam was arbitrary, capricious and contrary to law.

II.

The jurisdiction of this court directly to review acts of the Secretary is set forth in 38 U.S.C. § 502 (Supp. V. 1993):

> An action of the Secretary to which section 552 (a)(1) or 553 of title 5 (or both) refers, other than an action relating to the adoption or revision of the schedule of ratings for disabilities under section 355 of title 38, is subject to judicial review. Such review shall be in accordance with [the Administrative Procedure Act] and may be sought only in the United States Court of Appeals for the Federal Circuit.

Section 552(a)(1) requires each agency to publish in the Federal Register, among other things, "substantive rules of general applicability . . . and statements of general policy or interpretations of general applicability . . . ." Section 553, captioned "Rule making," specifies the procedure for rulemaking.

Thus, we may directly review rules promulgated by the Department of Veteran's Affairs, including substantive rules of general applicability, statements of general policy

and interpretations of general applicability because these are all actions "to which section 552(a)(1) refers . . . ."

Section 551(4) of title 5 defines a rule as

> the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency.

As our predecessor court explained: "rule making is legislative in nature, is primarily concerned with policy considerations for the future rather than the evaluation of past conduct, and looks not to the evidentiary facts but to policy-making conclusions to be drawn from the facts." *American Express Co. v. United States,* 472 F.2d 1050 (C.C.P.A. 1973) (citations omitted) .

These definitions cover the Secretary's determination not to establish a presumption-of-service connection with respect to prostate, liver, and nose cancer and the veteran's exposure to herbicides in Vietnam, and therefore we have jurisdiction to review it. The determination was a rule because it was a "statement of general . . . applicability and future effect designed to implement . . . or prescribe . . . law or policy . . . ." It prescribed the basis on which the Department would adjudicate every claim seeking disability or survivor benefits for specified diseases allegedly caused by exposure to herbicides in Vietnam. It reflects the result of a process that was "legislative in nature, [was] primarily concerned with policy considerations for the future . . ., and look[ed] . . . to policy-making conclusions to be drawn from the facts." Congress delegated to the Secretary the authority to determine whether or not to create a presumption of service connection between certain diseases and military service in Vietnam, and that determination would control the decisions in all subsequent cases involving the issue.

The Secretary contends that his determination is not a substantive rule because it will not have binding effect, since a claimant may establish service connection for any disease or injury by showing that it was incurred in service. Not only is this position unrealistic, but it is inconsistent with the reasons that led Congress in the 1984 Act to adopt the procedure of the Secretary creating presumptions of service connection for various diseases associated with herbicide exposure. Congress did so because it recognized that ordinarily it would be impossible for an individual veteran to establish that his disease resulted from exposure to herbicides in Vietnam.

Relying on the statement in *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991) that "a rule is substantive when it effects a change in existing law or policy which affects individual rights and obligations," the Secretary contends that his determination was merely an announcement "that there would be *no* change in the existing law and policy regarding service connection for those diseases" (emphasis in original). The policy decision that the 1991 Act required the Secretary to make was whether or not, under the Act's standards, to establish a presumption of service connection for various diseases. The Secretary's determination not to establish a presumption for a particular disease was just as much a change in policy as his determination to establish a presumption for another disease. Until the Secretary had acted, there was no existing law regarding presumptions for the Department to follow. The Secretary changed existing law by establishing or refusing to establish a presumption.

The Supreme Court dealt with a similar issue in *Frozen Food Express v. United States*, 351 U.S. 40 (1956). That case involved the exception in § 203(b)(6) of the Interstate Commerce Act, 49 Stat. 543 (1935), from the requirement that motor carriers have certificates of

public convenience and necessity, to carry "agricultural commodities."

"After an investigation instituted on its own motion [which included an evidentiary public hearing], the Commission issued an order that specified commodities are not 'agricultural' within the meaning of § 203(b)(6)." *Id.* at 41. The order incorporated findings from an accompanying report that "list[ed] those commodities that the Commission [found] exempted under § 203(b)(6) and those that are not." *Id.* at 42. The order did not, however, direct carriers hauling the commodities declared non-exempt to comply with the certificate requirement. *Id.* at 45 (Harlan, J., dissenting).

Frozen Food Express, a motor carrier that was transporting commodities that the Commission had ruled were not "agricultural commodities" (and therefore required a certificate), filed suit before a three-judge district court challenging the Commission's ruling. The district court "dismissed the action, saying that the 'order' of the Commission was not subject to judicial review," *id.* at 43, because "the 'order' was no more than a report of an investigation . . . 'which does not command the carrier to do, or to refrain from doing anything.'" *Id.* (quoting *United States v. L.A.R. Co.*, 273 U.S. 299 (1927)).

The Supreme Court reversed, holding that the Commission's action was reviewable. It stated:

> The determination by the Commission that a commodity is not an exempt agricultural product has an immediate and practical impact on carriers who are transporting the commodities, and on shippers as well. The "order" of the Commission warns every carrier, who does not have authority from the Commission to transport those commodities, that it does so at the risk of incurring criminal penalties. § 222(a). Where unauthorized operations occur, the Commission may proceed administratively and issue a cease and desist order. § 204(c). The determina-

> tion made by the Commission is not therefore abstract, theoretical, or academic. The "order" of the Commission which classifies commodities as exempt or nonexempt is, indeed, the basis for carriers in ordering and arranging their affairs. The "order" of the Commission is in substance a "declaratory" one, see 60 Stat. 240, 5 U.S.C. § 1004(d), which touches vital interests of carriers and shippers alike and sets the standard for shaping the manner in which an important segment of the trucking business will be done.

Id. at 43-44 (citations omitted).

That reasoning covers the present case. The Secretary's determination not to establish a presumption of service connection for prostate, liver and nose cancers "has an immediate and practical impact" on Vietnam veterans and their survivors who claim benefits on the ground that the veterans' cancers resulted from exposure to herbicides, was not "abstract, theoretical, or academic," "touches vital interests of" veterans and their survivors, and "sets the standard for shaping the manner in which an important segment" of the Department's activities "will be done."

"[J]udicial review of executive action 'will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress.' " *De Martinez v. Lamagno*, 115 S. Ct. 2227, 2231 (1995) (citation omitted). Not only is there no showing that Congress so intended, but the few references to the subject in the legislative history of the 1991 Act support reviewability. During the debate on the 1991 Act, Senator Daschle stated that

> the Secretary's determination that a particular disease does not warrant a presumption of service connection would be subject to judicial review. For example, the Secretary's published determination that a presumption of service connection is not warranted

> for a particular disease clearly seems to be a "statement of general policy . . . subject to judicial review under the Veterans Judicial Review Act."

137 Cong. Rec. S1271 (daily ed. January 30, 1991). Senator DeConcini, the floor manager, agreed "that such a determination would be reviewable." *Id. Accord* 137 Cong. Rec. H731 (daily ed. Jan. 29, 1991) (statement of Rep. Evans). Moreover, in the 1984 Act, which first required the Secretary to determine whether a presumption was warranted, one of the bill's primary sponsors stated:

> The Administrator's compliance with the required process, as well as any regulations issued by the Administrator would be subject to judicial review.
>
> I cannot overstate the importance of judicial review. . . It is only just that . . . Vietnam veterans have their day in court.

130 Cong. Rec. 13,155 (remarks of Senator Specter).

There is a well-settled presumption that agency actions are reviewable. *See McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 496 (1991); *Wheeler v. United States*, 11 F.3d 156, 159 (Fed. Cir. 1993). Nothing the Secretary relies on refutes that presumption. The Secretary's determination is reviewable.

III.

A. The 1991 Act created an unusual administrative scheme by which the Secretary is to determine whether there is a service connection between particular diseases and herbicide exposure in Vietnam. Unlike the typical responsibility assigned to government agency, the Secretary was directed to enter into an agreement with the Academy, a private non-government scientific agency, for the latter to summarize and assess the scientific evidence dealing with the issue and report its findings to him. The major work involved thus was assigned to a non-

government entity; the Academy was given 18 months to submit its report, but the Secretary was to render his decision within 60 days of receiving the report.

Following the receipt of the Academy's report, and obviously giving it great weight, the Secretary was to determine, for each of the diseases involved, whether there was a "positive association" between exposure of people to a herbicide agent and the existence of the disease. The standard for determining whether a positive association exists is whether the "credible evidence" for the association equals or outweighs the credible evidence against it. If the Secretary finds a credible association for a particular disease, he must establish a presumption of service connection for it.

The statutory scheme contemplates that the Academy's findings on these medical and scientific issues reflected in the Report would be the key element in the Secretary's decision. Congress necessarily intended that the Secretary, although not bound by the Academy's findings, would place great reliance on them.

Under the Administrative Procedure Act, we review the Secretary's decision to determine whether it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." 5 U.S.C. § 706(2)(A). This is a "highly deferential" standard of review. *Ethyl Corp. v. EPA*, 541 F.2d 1, 34 (D.C. Cir.), *cert. denied sub. nom.*, 426 U.S. 941 (1976). Under the unusual statutory scheme here involved, with the function of reviewing and evaluating the scientific evidence given to a non-governmental, independent scientific entity, an extremely strong showing of error would be required before we properly could reverse the Secretary's determination.

B. The petitioners make a sweeping attack on the evidentiary basis for the Secretary's findings and determinations. Although the argument is framed mainly in terms of the Secretary's alleged failure to consider the evidence in the Academy Report that indicated a positive associa-

tion between the three cancers involved and herbicide exposure, it really asserts that the Secretary erred because he did not give sufficient weight to that evidence. In essence the petitioners urge us to reweigh the evidence and come to a different conclusion than the Secretary reached.

Our role, however, "is not to substitute our judgment for that of the" Secretary. *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 43 (1983). Instead, we consider whether the Secretary has "examine[d] the relevant facts and articulate[d] an adequate explanation for [his] action including a rational connection between the facts found and the choice made. . . . [and] whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* As we show in Part IV, the Secretary's decision refusing to establish a presumption of service connection for the three cancers must stand.

The Secretary did not uncritically accept or merely rubber-stamp the Academy's factual findings. Instead, he carefully reviewed the evidentiary bases for them, recognizing the strengths and weaknesses of the underlying scientific studies that the Academy discussed. As the Academy had urged, he did not view the report's categorization of the diseases according to the strength of statistical association "as recommendations regarding DVA policy." Instead of merely applying the presumption to whole categories, the DVA task force, and then the Secretary, examined each disease to determine if it met the statutory standard. "The task force spent a great deal of time focusing on" the diseases in the Academy's second category, Limited/Suggestive Evidence of an Association, and determined that two of those diseases, respiratory cancers and multiple myeloma met the standard, whereas prostate cancer did not. The Secretary followed this recommendation, thus demonstrating independent judgment by recognizing that the Academy's factual conclu-

sions did not equate to the ultimate decision entrusted to him.

The petitioners rely to a considerable extent upon two declarations by experts in biostatistics and toxicology (Drs. Levin and Legator), which they filed with their opening brief. Those declarations, however, were not part of the record on which the Secretary based his decision, and are not part of the record before this court. Indeed, this court denied the petitioners' motion to supplement the administrative record with those declarations. We therefore do not consider them.

C. A major ground of the petitioners' challenge to the Secretary's evaluation of the evidence is that the Secretary improperly failed to recognize that the number of scientific studies showing a positive association between herbicide exposure and each of the three cancers was greater than the number showing no association or a negative association. According to the petitioners, the numerical superiority of this evidence required the Secretary to treat it as credible evidence of an association. They point out that the statutory evidentiary standard the Secretary is to apply in making his findings on whether a positive association exists is whether "credible evidence" for an association equals or outweighs the credible evidence against it. The statute does not define "credible evidence."

In evaluating evidence, however, the critical question is its quality, not its quantity. Just as "numerical superiority of witnesses alone could not necessarily entitle the plaintiff to relief," *Banks Construction Company v. United States*, 364 F.2d 357, 362 (Ct. Cl. 1966), so numerical superiority of scientific studies does not require the trier of fact to accept them.

The Department task force that reviewed the Academy Report anticipated and explained the reasons for rejecting the numerically-superior documents:

> it is likely that there will be controversy surrounding any conclusion about which evidence is credible and

> which evidence is less so or not credible. This is clearly demonstrated by the statements of Mark Venuti of the National Veterans Legal Services Project which have been endorsed by the Vietnam Veterans of America. Many readers of the NAS report will consider all positive evidence equally "credible" despite the confidence limits of the studies or the statistical significance of the findings. There will be a tendency to look at the charts prepared by the NAS and count up those studies which could be interpreted as positive and balancing them against cited studies showing no association or a negative association. This was not the purpose of those charts and the NAS staff and representatives of the Committee responsible for the report findings refused to interpret their findings that way either in the report or in face-to-face meetings with VA staff or at Congressional hearings.

The Secretary explained why he rejected the petitioners' approach:

> Simply comparing the number of studies which report a negative relative risk for a particular condition is not a valid method for determining whether the weight of evidence overall supports a finding that there is or is not a positive association between herbicide exposure and the subsequent development of the particular condition. Because of difference in statistical significance, confidence levels, control for confounding factors, etc., some studies are clearly more credible than others, and the Secretary has given them more weight in evaluating the overall credibility of the evidence concerning specific diseases.

59 F.R. 342.

There is no basis for assuming that, by using the term "credible evidence" in the 1991 Act, Congress intended to preclude the Secretary from applying the traditional principle that the critical issue in evaluating evidence is its

quality, not its quantity. The Secretary cannot be faulted for refusing to follow the more numerous studies that support the petitioners' contentions.

D. The petitioners challenge the Secretary's refusal to establish a presumption of service connection for liver and nose cancer because he did not discuss the biologic plausibility of an association between those diseases and herbicide exposure. The 1991 Act provides that "[f]or each disease reviewed, the Academy shall determine . . . whether there exists a plausible biological mechanism or the evidence of a causal relationship between herbicide exposure and the disease." 38 U.S.C. § 1116, note d. Although the Act did not require the Secretary to address this factor, it required him to consider the Academy report, which he admittedly did. The petitioners contend that by implication the Act required him also to discuss biologic plausibility.

The fact that the 1991 Act expressly required the Academy to consider biologic plausibility but did not impose a similar requirement on the Secretary is a strong indication that the latter was not required to do so. *Russello v. United States,* 464 U.S. 16, 23 (1983) (" '[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion' " (citation omitted)). This is particularly so because the Act specified in detail exactly what were the precise duties of the Academy and the Secretary, and provided specific standards for each of them to follow. If Congress had intended the Secretary specifically to consider biologic plausibility, it is a reasonable assumption that it would have told him to do so—as it did for the Academy.

The Academy Report discussed biologic plausibility, but concluded that "there is as yet no convincing evidence of, or mechanistic basis for, the carcinogenicity of any of the herbicides used in Vietnam." The Report also addressed

the carcinogenicity of dioxin, a contaminant "found in varying levels in different batches of Agents Orange, Pink, Purple, and Green," and reported extensive evidence that dioxin caused cancer in laboratory animals. Although the carcinogenicity of an herbicide contaminant could be viewed as credible evidence of a positive association, the Secretary could reasonably conclude otherwise. This is especially so because Congress directed that the Academy was specifically to address "whether there exists a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the disease," and the presence of dioxin in an herbicide does not compel the conclusion that there was such a relationship caused by exposure to the herbicide.

IV.

We turn to the Secretary's refusal to establish a presumption of service connection for the three cancers involved.

1. The Secretary stated the following with regard to prostate cancer:

> The NAS report assigns prostate cancer to a category labeled limited/suggestive evidence of an association, which it defined as meaning there is evidence suggestive of an association between herbicide exposure and a particular health outcome, but that evidence is limited because chance, bias, and confounding could not be ruled out with confidence. Prostate cancer is a very common male genitourinary cancer which shows marked increased prevalence with age. There are statistically significant occupational studies which show no association between prostate cancer and herbicide exposure (e.g., Fingerhut . . . ; Manz . . . ; Saracci . . . .). Some occupational studies have shown a slight elevated risk for prostate cancer among farm and forestry workers (e.g. Burmeister . . . ; Alavanja . . .); however, only one study concerning

> a small sub-set of farmers (Morrison . . .) associated the increased risk of prostate cancer among farmers specifically with herbicide exposure. The Morrison study is so recent that it is too early to determine whether its results will be replicated by other research. Accordingly, the Secretary has found that the credible evidence against an association between prostate cancer and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

59 F.R. 242 (1994).

The Secretary's decision accurately analyzes and summarizes the Academy's findings and is reasonable in light of that analysis. In placing prostate cancer in the "limited/suggestive evidence of an association" category, the Academy pointed out:

> Most of the agricultural studies indicate some elevation in risk of prostate cancer. One large well-done study in farmers showed an increased risk, and subanalyses in this study indicate that the increased risk is specifically associated with herbicide exposure. The three major production worker studies . . . all show a small, but not statistically significant elevation in risk. . . . It should be noted, however, that most of the associations are relatively weak (< 1.5).

The petitioners point out, and the Secretary concedes, that he erred in citing the Fingerhut, Manz, and Saracci studies as supporting the statement that "[t]here are statistically significant occupational studies which show no association between prostate cancer and herbicide exposure." Instead, the three studies actually show a positive association, but are not statistically significant. The quoted portion of the statement, however, is not inaccurate. It would have been accurately supported if the Secretary had cited to the Ronco and Wicklund studies, which were statistically significant and showed a negative association and none at all, respectively.

We will "not reverse simply because there are uncertainties, analytical imperfections, or even mistakes in the pieces of the picture petitioners have chosen to bring to [our] attention . . . but only when there is such an absence of overall rational support as to warrant the description arbitrary and capricious." *Center for Auto Safety v. Peck*, 751 F.2d 1336, 1370 (D.C. Cir. 1985) (citation omitted). In this case, the Secretary's miscitation of the three studies does not so undermine the Secretary's rationale as to render it arbitrary and capricious.

The petitioners also contend that the Secretary erred in characterizing the Morrison study as a small subset. The Academy Report shows that the Secretary's statement is accurate. His statement referred to a subset of the study that covered only 20 cases of exposure to herbicides. The Secretary reasonably could have concluded that because the entire study covered 1,138 cases of exposure, this was but a small segment of the study.

The petitioners further object to the Secretary's statement that it is "too early to determine whether [Morrison's] results will be replicated by other research." They contend that this statement indicates that the Secretary misconstrued his statutory mandate to consider whether the studies are capable of replication. The Secretary's statement merely reflects the Morrison study's warning that the results "should be considered tentative because of the relatively low increases in risk and because an association has not been noted previously." The Secretary reasonably recognized that future research on the issue might undermine or contradict the conclusions of the Morrison study. Indeed, a further Academy report on prostate cancer was due in July 1995.

The petitioners make various arguments concerning the relative merits of the studies the Academy considered. As noted, however, it is not our function to reweigh the evidence. The Secretary's decision is reasonable based on

the Academy's factual determinations, particularly its finding that almost all studies, certainly all statistically significant ones, show a weak positive association at best.

B. The Secretary stated with regard to hepatobiliary (liver) cancers

> The NAS reports assigns . . . hepatobiliary cancers . . . to a category labeled inadequate/insufficient evidence to determine whether an association exists, which is defined as meaning that the available studies are insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association with herbicide exposure.
>
> . . .
>
> Hepatobiliary cancers are cancers of the liver and bile duct. There are a variety of risk factors that should be considered by a credible study, including hepatitis B and C, alcohol abuse, cirrhosis, exposure to . . . PCB, and smoking. The relevant studies are few and have not adequately controlled for these risk factors. A Swedish case control study (Hardell . . . 1984 . . .) showed a relationship between herbicide exposure and the subsequent development of hepatobiliary cancer; however, other studies of similar size (Ronco . . . 1992 . . .; Wiklund . . . 1983 . . .) indicated no relationship. A large occupational study (Fingerhut et al, 1991) and a study of farmers in Denmark and Italy (Ronco 1992) found no relationship. Accordingly, the Secretary has found that the credible evidence against an association between hepatobiliary cancer and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

59 F.R. 343 (1994).

The Academy Report summarized the various studies as follows:

> There are relatively few occupational, environmental, or veterans studies of liver cancer (Table 8-6), and most of these are small in size and have not controlled for life-style-related risk factors. One of the largest studies (Hardell et al., 1984) indicates an increased risk for liver cancer and exposure to herbicides, but another study of Swedish agricultural workers (Wiklund, 1983) estimates a relative risk that is significantly less than 1.0 [i.e. a protective association]. The estimated relative risks from other studies are both positive and negative. As a whole, given the methodological difficulties associated with most of the few existing studies, the evidence regarding liver cancer is not convincing with regard to either an association with herbicides/TCDD or the lack of an association.

The petitioners contend that the Secretary erred in stating that there were few studies. This statement, however, reflects the Academy's statement based on the 18 studies that it examined. The petitioners cite no other studies that they contend the Secretary also should have considered.

According to the petitioners, the Secretary erred in failing to consider that nine studies are in favor of association, that eight are against it and that one finds no association. Instead, the Secretary relied on the studies with comparably sized samples, all of which were among the largest. Of the four he discussed, three do not show a positive association. Moreover, none of the 18 studies are statistically significant. Given this evidence, the Secretary reasonably concluded that the credible evidence against an association outweighed the credible evidence for one.

C. The Secretary stated with regard to nasal/naso-pharyngeal cancer:

The NAS report assigns . . . nasal/nasopharyngeal cancer to a category labeled inadequate/insufficient evidence to determine whether an association exists, which is defined as meaning that the available studies are insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association with herbicide exposure.

. . .

NAS noted an association between nasal cancers and occupational exposure to nickel and to chromates. Exposure to wood dust is also a risk factor for nasal cancers; smoking and exposure to formaldehyde may increase the risk associated with wood dust. There is also evidence that leather workers have an increased risk for nasal cancers and that there is an association betwen chronic nasal diseases and consumption of salt preserved foods. Most studies (e.g. Wiklund, 1983; Ronco et al. 1992) showed inconclusive results, and often did not control for confounding variables. Two other epidemiological studies based on the same three cases (Saracci et al., 1991. Coggon D., Pannett B., Winter P.D., Achedson E.D., Bonsall J., 1986. Mortality of workers exposed to 2 methyl-4-chlorophenoxyacetic acid. Scandinavian Journal of Work, Environment, and Health 12:448-454) and one case-control study (Hardell L., Johansson B. Axelson O., 1982. Epidemiological study of nasal and nasopharyngeal cancer and their relation to phenoxy acid or chlorophenol exposure. American Journal of Industrial Medicine 3 247-257) showed increased risk associated with herbicide exposure. However, that risk was not statistically significant, which diminishes the importance of these studies. Accordingly, the Secretary has found that the credible evidence against an association between nasal/nasopharyngeal cancers and herbicide exposure outweighs the credible evi-

> dence for such an association, and he has determined that a positive association does not exist.

59 F.R. 346 (1994).

The Secretary's discussion again echoed the Academy's Report, which discussed numerous factors and exposures to things other than herbicides that have been associated with an increased risk of nasal cancer. It summarized the epidemiological results much as the Secretary did, noting that the Saracci and Coggon studies were based on the same three cases and that the Hardell study "found [a positive association] for those exposed to phenoxy acids, based on eight exposed cases." It noted that a Center for Disease Control Study of Vietnam veterans found no "significant associations for Vietnam service," and that "[o]ther studies show[ed] inconclusive results." It summarized the epidemiologic evidence as "inadequate or insufficient . . . to determine whether an association exists between exposure to herbicides and nasal/nasopharyngeal cancer."

Aside from the biologic plausibility and numerical arguments previously discussed, the petitioners contend that the Secretary made two key errors with regard to nasal cancers. They contend that the Secretary (as did the Academy) mistakenly stated that the Sarraci and Coggon studies were based on the same three cases. Even if this statement was wrong, however, it did not render the Secretary's decision arbitrary or capricious. Neither he nor the Academy attached any significance to the supposedly-shared samples, but only noted the fact. It does not appear to have influenced the Secretary's conclusion. Instead, he focused on the inconclusive nature of the studies discussed, citing their lack of significance.

The petitioners also contend that the Secretary's decision was arbitrary and capricious because it did not discuss a subset of the Hardell study that showed a positive

association between chlorophenol exposure and nasal cancer. The Secretary's decision discusses the Hardell study in terms of what it shows regarding "the risk associated with herbicide exposure." This shows that he was aware of the Hardell study, but considered only the part dealing with herbicide exposure. Other than the inclusion of the subset in a table in the Academy's report, the petitioners offer no convincing reason why the chlorophenol subset was a relevant factor that the Secretary should have deemed credible evidence of a relationship between herbicide exposure and nasal cancer. They have thus failed to demonstrate that this was relevant evidence, and thus the Secretary's alleged failure to consider it would not be arbitrary and capricious. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971).

AFFIRMED.

APPENDIX B

[59 Fed. Reg. 341 (Jan. 4, 1994)]

DEPARTMENT OF VETERANS AFFAIRS

Diseases Not Associated With Exposure to Certain Herbicide Agents

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: As required by law, the Department of Veterans Affairs (VA) hereby gives notice that the Secretary of Veterans Affairs, under the authority granted by the Agent Orange Act of 1991, has determined that a presumption of service connection based on exposure to herbicides used in the Republic of Vietnam during the Vietnam era is not warranted for the following conditions: Prostate cancer, peripheral neuropathy, hepatobiliary cancers, bone cancers, female reproductive cancers, renal cancers, testicular cancer, leukemia, abnormal sperm parameters and infertility, cognitive and neuropsychiatric disorders, motor/coordination dysfunction, metabolic and digestive disorders, immune system disorders, circulatory disorders, respiratory disorders (other than lung cancer), nasal/nasopharyngeal cancer, skin cancer, gastrointestinal tumors, bladder cancer, brain tumors, and any other condition for which the Secretary has not specifically determined a presumption of service connection is warranted.

FOR FURTHER INFORMATION CONTACT: John Bisset, Jr., Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233-3005.

SUPPLEMENTARY INFORMATION: Section 3 of the Agent Orange Act of 1991, Public Law 102-4, 105 Stat. 11 (1991), directed the Secretary to enter into an

agreement with the National Academy of Sciences (NAS) to review the scientific evidence concerning the association between exposure to herbicides used in support of military operations in the Republic of Vietnam during the Vietnam era and each disease suspected to be associated with such exposure. Congress mandated that NAS determine, to the extent possible, (1) whether there is a statistical association between the suspect diseases and herbicide exposure, taking into account the strength of the scientific evidence and the appropriateness of the methods used to detect the association; (2) the increased risk of disease among individuals exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and (3) whether there is a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the suspect disease.

Section 2 of Public Law 102-4 provides that whenever the Secretary determines, based on sound medical and scientific evidence, that a positive association (i.e., the credible evidence for the association is equal to or outweighs the credible evidence against the association) exists between exposure of humans to an herbicide agent (i.e., a chemical in an herbicide used in support of the United States and allied military operations in the Republic of Vietnam during the Vietnam era) and a disease, the Secretary will publish regulations establishing presumptive service connection for that disease. If the Secretary determines that a presumption of service connection is not warranted, he will publish a notice of that determination, which includes an explanation of the scientific basis for that determination.

Although Public Law 102-4 does not define "credible", it does instruct the Secretary to "take into consideration whether the results are statistically significant, are capable of replication, and withstand peer review." Simply comparing the number of studies which report a positive

relative risk to the number of studies which report a negative relative risk for a particular condition is not a valid method for determining whether the weight of evidence overall supports a finding that there is or is not a positive association between herbicide exposure and the subsequent development of the particular condition. Because of differences in statistical significance, confidence levels, control for confounding factors, etc., some studies are clearly more credible than others, and the Secretary has given them more weight in evaluating the overall credibility of the evidence concerning specific diseases.

After reviewing approximately 6,420 abstracts of scientific or medical articles and selecting approximately 230 epidemiologic studies for detailed analysis, consulting with outside experts, and conducting public hearings, NAS issued a report, entitled "Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam", on July 27, 1993. The Secretary announced that same day that he had concluded that a positive association exists between exposure to herbicides used in the Republic of Vietnam and the subsequent development of Hodgkin's disease and porphyria cutanea tarda. Proposed regulations were published in the Federal Register on September 28, 1993 (See 58 FR 50528-30). The Secretary also announced that VA would review the remaining findings in the NAS report to determine whether a positive association exists between herbicide exposure and any other conditions. That review has been completed and this notice, pursuant to Public Law 102-4, conveys the Secretary's determination that there is no positive association between herbicide exposure and prostate cancer, peripheral neuropathy, hepatobiliary cancers, bone cancers, female reproductive cancers, renal cancers, testicular cancer, leukemia, abnormal sperm parameters and infertility, cognitive and neuropsychiatric disorders, motor/coordination dysfunction, metabolic and digestive disorders, immune system disorders, circulatory disorders, respiratory disorders (other

than lung cancer), nasal/nasopharyngeal cancer, skin cancer, gastrointestinal tumors, bladder cancer, brain tumors, and any other condition for which the Secretary has not specifically determined a presumption of service connection is warranted.

The NAS report assigns prostate cancer to a category labeled limited/suggestive evidence of an association, which it defined as meaning there is evidence suggestive of an association between herbicide exposure and a particular health outcome, but that evidence is limited because chance, bias, and confounding could not be ruled out with confidence. Prostate cancer is a very common male genitourinary cancer which shows marked increased prevalence with age. There are statistically significant occupational studies which show no association between prostate cancer and herbicide exposure (e.g., Fingerhut M.A., Halperin W.E., Marlow D.A., Piacitelli L.A., Honchar P.A., Sweeney M.H., Greife A.L., Dill P.A., Steenland K., Suruda A.J. 1991. Cancer mortality in workers exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin. New England Journal of Medicine 324:212-218; Manz A., Berger J., Dwyer J.H., Flesch-Janys D., Nagel S., Waltsgott H. 1991. Cancer mortality among workers in chemical plant contaminated with dioxin. Lancet 338:959-964; Saracci R., Kogevinas M., Bertazzi P.A., Bueno De Mesquita B.H., Coggon D., Green L.M., Kauppinen T., L'Abbe K.A., Littorin M., Lynge E., Mathews J.D., Neuberger M., Osman J., Pearce N., Winkelman R. 1991. Cancer mortality in workers exposed to chlorophenoxy herbicides and chlorophenois. Lancet 338:1027-1032). Some occupational studies have shown a slight elevated risk for prostate cancer among farm and forestry workers (e.g., Burmeister L.F., 1981. Cancer mortality in Iowa farmers: 1971-1978. Journal of the National Cancer Institute 66:461-464; Alavanja M.C., Merkle S., Teske J. Eaton B., Reed B. 1989. Mortality among forest and soil conservationists. Archives of Environmental Health 44:94-101); however, only one study concerning a small sub-

set of farmers (Morrison H., Savitz, D., Semenciw R., Hulka B., Mao Y., Morison D., Wigle D. 1993. Farming and prostate cancer mortality. American Journal of Epidemiology 137:270-280) associated the increased risk of prostate cancer among farmers specifically with herbicide exposure. The Morrison study is so recent that it it too early to determine whether its results will be replicated by other research. Accordingly, the Secretary has found that the credible evidence against an association between prostate cancer and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

The NAS report assigns peripheral neuropathy, hepatobiliary cancers, bone cancers, female reproductive cancers, renal cancers, testicular cancer, leukemia, abnormal sperm parameters and infertility, cognitive and neuropsychiatric disorders, motor/coordination dysfunction, metabolic and digestive disorders, immune system disorders, circulatory disorders, respiratory disorders (other than lung cancer), and nasal/nasopharyngeal cancer to a category labeled inadequate/insufficient evidence to determine whether an association exists, which is defined as meaning that the available studies are of insufficient quality, consistency, or statistical strength to permit a conclusion regarding the presence or absence of an association with herbicide exposure.

Peripheral neuropathy can be induced by many common medical and environmental disorders unrelated to herbicide exposure, such as aging, alcoholism, diabetes, and exposure to other toxic chemicals. The last time VA considered this issue, it determined, after receiving the advice of the Veterans' Advisory Committee on Environmental Hazards, that there was sufficient evidence to meet the requirements for a "significant statistical association," the standard in effect at that time, between exposure to herbicides containing dioxin and the subsequent development of peripheral neuropathy under certain circumstances

(See 57 FR 2236-38). That conclusion, however, relied heavily on case reports, which are anecdotal and have no statistical significant, and occupational studies such as Singer and colleagues (1982) (Singer R., Moses M., Valciukas J., Lilis R., Selikoff I.J., 1982. Nerve conduction velocity studies of workers employed in the manufacture of phenoxy herbicides. Environmental Research 29:297-311) whose credibility is compromised because they did not apply consistent methods to define a comparison group, determine exposure, evaluate clinical deficits, use standard definitions of peripheral neuropathy, or eliminate confounding variables. The Singer study, for example, excluded individuals with excessive alcohol consumption from the controls but not from the subjects of the study. Other occupational studies, such as Suskind and Herzberg (1984) (Suskind R.R., Hertzberg V.S., 1984. Human health effects of 2,4,5-T and its toxic contaminants. Journal of the American Medical Association 251:2372-2380), which did not have those methodological problems, showed no difference in the incidence of peripheral neuropathy for workers exposed to herbicides and workers not so exposed. Accordingly, the Secretary has found that the credible evidence against an association between peripheral neuropathy and herbicide exopsure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

Hepatobiliary cancers are cancers of the liver and bile duct. There are a variety of risk factors that should be considered by a credible study, including hepatitis B and C, alcohol abuse, cirrhosis, exposure to polychlorinated biphenyl (PCB), and smoking. The relevant studies are few, and have not adequately controlled for these risk factors. A Swedish case control study (Hardell L., Bengtsson N.O., Jonsson U., Eriksson S., Larsson L.G., 1984. Aetiological aspects on primary liver cancer with special regard to alcohol, organic solvents and acute intermittent porphyria: an epidemiological investigation. British Jour-

nal of Cancer 50:389-397) showed a relationship between herbicide exposure and the subsequent development of hepatobiliary cancer; however, other studies of similar size (Ronco G, Costa G., Lynge E., 1992. Cancer risk among Danish and Italian farmers. British Journal of Industrial Medicine 49:220-225; Wiklund K., 1983. Swedish agricultural workers: a group with a decreased risk of cancer. Cancer 51:566-568) indicated no relationship. A large occupational study (Fingerhut et al., 1991) and a study of farmers in Denmark and Italy (Ronco et al., 1992) found no relationship. Accordingly, the Secretary has found that the credible evidence against an association between hepatobiliary cancer and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

Bone cancers were considered together with joint cancers by NAS. Because of the rarity of bone cancers, most studies have been too small to detect a significant risk. There has not been a consistent finding of bone cancer in exposed groups; the preponderance of studies show no association, and the few studies that demonstrate a positive relationship (Fingerhut et al., 1991; Breslin P., Kang H., Lee y., Burt V., Shepard B.M., 1988. Proportionate mortality study of U.S. Army and U.S. Marine Corps veterans of the Vietnam War. Journal of Occupational Medicine 30:412-419) are small and have large confidence intervals which include one. The small size of the studies and the confidence limitations compromise their significance. Accordingly, the Secretary has found that the credible evidence against an association between bone cancers and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

Female reproductive cancers reviewed by NAS include those of the breast, uterus, cervix, ovary, and other genital malignancies. The data related to women and herbicide exposure is extremely limited because few of the studies

included women. A large number of the breast cancer studies showed no association. Two studies (Thomas T.L., Kang H., Dalager N., 1991. Mortality among women Vietnam veterans, 1973-1987. American Journal of Epidemiology 134:973-980; Manz et al., 1991) showed an increased risk for breast cancer which was not significant since both studies failed to control for reproductive histories and had methodological problems. Only one small case control study (Donna A., Betta P-G., Robutti F., Crosignani P., Berrino F., Bellingeri D., 1984. Ovarian mesothelial tumors and herbicides: a case control study. Carcinogenesis 5:941-942) showed an association with ovarian cancer, but the confidence intervals were very wide. The larger occupational and farm worker studies all showed significantly lower mortality ratios than expected. Likewise, studies of exposures generally found less uterine and cervical cancer than expected. Accordingly, the Secretary has found that the credible evidence against an association between female reproductive cancers and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

The leather industry, asbestos, cadmium, petroleum products, analgesics, smoking, and obesity have been associated with renal cancers. Studies of renal cancer have generally produced inconclusive results, in some cases because of failure to adequately control for these confounding factors. Only one study of agricultural and forest workers (Alavanja et al., 1989) showed a significantly increased risk of death from renal cancers; however, the preponderance of studies, including the two largest (Wiklund, 1983; Burmeister, 1981), showed either no relationship with renal cancers or increased risk which was not significant. Accordingly, the Secretary has found that the credible evidence against an association between renal cancers and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

Major risk factors for testicular cancer are undescended testis and other factors, such as genetic abnormalities, infections, etc., which produce atrophy and dysfunction. In general, occupational studies (Ronco et al., 1992; Wiklund, 1983) have shown no association between herbicide exposure and testicular cancer. Occupational and environmental studies have found either no association or increased risk which was not significant. Studies concerning Vietnam veterans were inconsistent, and in those that found increased risk, that risk was generally not significant. Accordingly, the Secretary has found that the credible evidence against an association between testicular cancer and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

Potential evidence for an association between herbicide exposure and leukemia comes primarily from studies of farmers (Ronco et al., 1992; Wigle D.T., Semenciw R.B., Wilkins K., Riedel D., Ritter L., Morrison H.I., Mao Y., 1990. Mortality study of Canadian male farm operators: non-Hodgkin's lymphoma mortality and agricultural practices in Saskatchewan. Journal of the National Cancer Institute 82:575-582) and residents of Seveso, Italy (Bertazzi P.A., Zocchetti C., Pesatori A.C., Guercilena S., Sanarico M., Radice L., 1989b. Ten-year mortality study of the population involved in the Seveso incident in 1976. American Journal of Epidemiology 129:1187-1200; Bertazzi P.A., Zocchetti C., Pesatori A.C., Guercilena S., Consonni D., Tironi A., Landi M.T., 1992. Mortality of a young population after accidental exposure to 2,3,7,8-tetrachlorodibenzodioxin. International Journal of Epidemiology 21:118-123). The studies of farmers did not control for other confounding exposures (Brownson R.C., Reif J.S., Chang J.C., Davis J.R., 1989. Cancer risk among Missouri farmers. Cancer 64:2381-2385.; Brown L.M., Blair A., Gibson R., Everett G.D., Cantor K.P., Schuman L.M., Burmeister L.F., Van Lier S.F., Dick F. 1990. Pesticide exposures and other agricultural

risk factors for leukemia among men in Iowa and Minnesota. Cancer Research 50:6585-6591). When farmers were stratified by suspected herbicide exposure, the incidence of leukemia was generally not elevated. Any elevation appeared to be due to factors other than herbicide exposure, e.g., risk was higher among chicken farmers than wheat farmers (Alavanja M.C., Blair A, Merkle S., Teske J. Eaton B., 1988. Mortality among agricultural extension agents. American Journal of Industrial Medicine 14:167-176). The suggestive evidence of increased risk concerning Seveso, Italy was not significant because of the small number of actual cases in which leukemia was found. Since none of the studies demonstrated a dose-response for any subtype of leukemia, it is not possible to attribute leukemia to herbicide exposure. Accordingly, the Secretary has found that the credible evidence against an association between leukemia and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

The common parameters used to evaluate toxic effects to sperm are number, motility, structure, and morphology. Many chemicals have been implicated in interfering with motility and sperm structure (Wyrobek A.J., Gordon L.A., Burkhart J.G., Francis M.W., Kapp R.W., Letz G., Malling H.V., Topham J.C., Whorton M.D., 1983. An evaluation of human sperm as indicators of chemically induced alterations of spermatogenic function. A report of the U.S. Environmental Protection Agency Gene-Tox Program. Mutation Research 115:73-148). One occupational study (Lerda D., Rizzi R., 1991. Study of reproductive function in persons occupationally exposed to 2,4-dichlorophenoxyacetic acid (2,4-D). Mutation Research 262:47-50) and one study of Vietnam veterans (Air Force Health Study (AFHS), 1992. An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides. Reproductive Outcomes. Brooks AFB: USAF School of Aerospace

Medicine. AL-TR-992-0900 602 pp.) found no association with decreased sperm count. Another study of Vietnam veterans (Centers for Disease Control (CDC), 1989. Comparison of Serum Levels of 2,3,7,8-Tetrachlorodibenzo-p-dioxin with Indirect Estimates of Agent Orange Exposure Among Vietnam Veterans: Final Report. Atlanta: U.S. Department of Health and Human Services) found lower sperm concentration and reduced sperm motility, but suggested these outcomes may be associated with the Vietnam experience rather than exposure to herbicides. Infertility usually incorporates two concepts: the inability to conceive and the inability to produce live children. Most studies do not take into account the desire for children, contraceptive practices, and other factors influencing fertility. NAS found no occupational or environmental studies examining herbicide exposure and infertility, and veteran studies (Field B., Kerr C., 1988. Reproductive behavior and consistent patterns of abnormality in offspring of Vietnam veterans. Journal of Medical Genetics 25:819-826; AFHS, 1992; Centers for Disease Control (CDC), 1988. Health status of Vietnam veterans. III. Reproductive outcomes and child health. Journal of the American Medical Association 259:2715-2717) do not support an association between herbicide exposure and infertility. Accordingly, the Secretary has found that the credible evidence against an association between abnormal sperm parameters and infertility and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

Studies of cognitive and neuropsychiatric disorders are beset by a number of methodologic problems, including exposure measures, the wide variety of "standardized" test instruments used, and the inability to detect or correct for other influences on test results such as emotional state, non-neurologic disease, metabolic conditions, fatigue, medications, or style of the examiner. Because of their failure to adequately control for these confounding factors,

these studies lack credibility in assessing the relationship of herbicide exposure to these conditions. Accordingly, the Secretary has found that there is no credible evidence for an association between cognitive and neuropsychiatric disorders and herbicide exposure, and he has determined that a positive association does not exist.

There were no significant studies available to analyze whether an association exists between herbicide exposure and motor/coordination dysfunction. Accordingly, the Secretary has found that there is no credible evidence for an association between motor/coordination dysfunction and herbicide exposure, and he has determined that a positive association does not exist.

Metabolic and digestive disorders (diabetes mellitus, hepatic enzyme abnormality, lipid abnormalities, and ulcers) were also categorized by NAS as health outcomes with inadequate/insufficient evidence to determine whether an association exists. Although NAS found no biologic basis to suspect an association between herbicide exposure and diabetes, abnormal glucose tolerance tests have been reported in three studies (Sweeney M.H., Fingerhut M.A., Arezzo J.C., Hornung R.W., Connally L.B. In press. Peripheral neuropathy after occupational exposure to 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD); Air Force Health Study. 1991. An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides. Serum Dioxin Analysis of 1987 Examination Results. Brooks AFB, TX: USAF School of Aerospace Medicine. 9 vols.; Pazderova Vejlupkova J., Lukas E., Nemcova M., Pickova J., Jirasek L., 1991. The development and prognosis of chronic intoxication by tetrachlorodibenzo-p-dioxin in men. Archives of Environmental Health 36:5-11). While this suggests such an association, the evidence is inconclusive and its credibility is questionable because an abnormal glucose tolerance test is not an absolute indicator of diabetes and none of these studies allowed for the confounding role of obesity. Two other studies found no association (Moses M., Lilis

R., Crow K.D., Thornton J., Fischbein A., Anderson H.A., Selikoff I.J., 1984. Health status of workers with past exposure to 2,3,7,8-tetrachlorodibenzo-p-dioxin in the manufacture of 2,4,5-trichlorophenoxyacetic acid: Comparison of findings with and without chloracne. American Journal of Industrial Medicine 5:161-182; Suskind and Hertzberg, 1984), and a number of studies have shown no increased death rates from diabetes (Bertazzi et al., 1989) Cook R.R., Bond G.G., Olson R.A., Otto M.G., 1987. Update of the mortality experience of workers exposed to chlorinated dioxins. Chemosphere 16:2111-2116; Henneberger P.K., Ferris B.G. Jr., Monson R.R., 1989. Mortality among pulp and paper workers in Berlin, New Hampshire. British Journal of Industrial Medicine 46:658-664). Accordingly, the Secretary has found that the credible evidence against an association between diabetes and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive associations does not exist.

The studies related to hepatic enzyme abnormality did not demonstrate an association with liver disease, and confounding factors (alcohol abuse, cirrhosis, hepatitis, and other toxic chemicals) were not ruled out. Studies showing lipid abnormalities do not control for the confounding variables of obesity and genetic factors, and no medical significance of the modest and variable increases has been demonstrated. The risk of gastric ulcers in exposed populations has not been sufficiently studied to establish an association with herbicide exposure. Only one study (Suskind and Hertzberg, 1984) indicates any increase, and in that study it is difficult to rule out the many factors (e.g., alcoholism, non-steroidal anti-inflammatory drugs, and H. pylori infection) known to be associated with ulcers. Accordingly, the Secretary has found that there is no credible evidence for an association between metabolic and digestive disorders (other than diabetes) and herbicide exposure, and he has determined that a positive association does not exist.

The available data deal with two categories of immune system disorders: immune modulation and autoimmunity. Many immune parameters have been studied; however, few show a relationship to herbicide exposure. Most studies address such a wide range of immune parameters that it is likely that at least some of the positive results are due to chance alone, which undermines the credibility of those studies. Furthermore, the clinical meaning, i.e., the relationship of immune disorders to disease, is unclear. Other studies (e.g., Pocchiari F., Silano V., Zampieri A., 1979. Human health effects from accidental release of tetrachlorodibenzo-p-dioxin (TCDD) at Seveso, Italy. Annals of the New York Academy of Sciences 320:311-320; Ghezzi I., Cannatelli P., Assennato G., Merlo F., Mocarelli P., Brambilla P., Sicurello F., 1982. Potential 2,3,7,8-tetrachlorodibenzo-p-dioxin exposure of Seveso decontamination workers. A controlled prospective study. Scandinavian Journal of Work, Environment, and Health 8:176-179) found no relationship between immune system disorders and herbicide exposure. Accordingly, the Secretary has found that the credible evidence against an association between immune system disorders and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

Most occupational studies concerning circulatory disorders (e.g., Moses et al., 1984; Suskind and Hertzberg, 1984) showed no increased mortality or morbidity from circulatory disorders after herbicide exposure. The studies of the residents of Seveso, Italy (Bertazzi, P.A., Zocchetti C., Pesatori A.C., Guercilena S., Sanarico M., Radice L., 1989a. Mortality in an area contaminated by TCDD following an industrial incident. Medicina Del Lavoro 80:316-329; Bertazzi et al., 1989b) showed some increased risk of mortality in the first five year follow-up; however, these studies had a number of technical problems: they were not specific to circulatory disease and did not control for the confounding variables of smoking,

diabetes, and hypertension. Veteran studies (e.g., CDC, 1988) have suggested that any increase in heart disease may be associated with the Vietnam experience rather than herbicide exposure, and most of these studies did not adjust for confounding variables. Accordingly, the Secretary has found that the credible evidence against an association between circulatory diseases and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a postitive association does not exist.

NAS examined studies that covered a wide variety of respiratory disorders (e.g., chronic bronchitis, asthma, pleurisy, pneumonia, and tuberculosis), other than respiratory cancer. Studies of individuals exposed in occupational settings revealed no increase in mortality from respiratory disease (Coggon D., Pannett B., Winter P., 1991. Mortality and incidence of cancer at four factories making phenoxy herbicides. British Journal of Industrial Medicine 48:173-178; Blair A., 1983. Lung cancer and other causes of death among licensed pesticide applicators. Journal of the National Cancer Institute 71:31-37; Alavanja et al., 1989; Coggon D., Pannett B., Winter P.D., Acheson E.D., Bonsall J., 1986. Mortality of workers exposed to 2-methyl-chlorophenoxyacetic acid. Scandinavian Journal of Work, Environment, and Health 12:448-454). Environmental exposure studies similarly showed no significant differences in mortality due to respiratory disease (Bertazzi et al., 1989a,b). Also, mortality studies of Vietnam veterans generally found no increased risk.

Morbidity data are generally difficult to evaluate because of methodological problems and because studies focused on symptoms, lung function tests and x-ray interpretation rather than disease (e.g., Calvert et al., 1991; Pollei S., Mettler F.A. Jr., Kelsey C.A., Walters M.R., White R.E., 1986. Follow-up chest radiographs in Vietnam veterans: Are they useful? Radiology 161:101-102). One occupational study (Calvert G.M., Sweeney M.H., Morris J.A., Fingerhut M.A., Hornung R.W., Halperin W.E., 1991.

Evaluation of chronic bronchitis, chronic obstructive pulmonary disease, and ventilatory function among workers exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin. American Review of Respiratory Disease 144:1302-1306) showed no excess morbidity; another occupational study (Suskind and Hertzberg, 1984) found increased symptomatology of respiratory disease, but did not adequately control for the confounding factor of age. Accordingly, the Secretary has found that the credible evidence against an association between respiratory disorders and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

NAS noted an association between nasal cancers and occupational exposure to nickel and to chromates. Exposure to wood dust is also a risk factor for nasal cancers; smoking and exposure to formaldehyde may increase the risk associated with wood dust. There is also evidence that leather workers have an increased risk for nasal cancers, and that there is an association between chronic nasal diseases and consumption of salt-preserved foods. Most studies (e.g., Wiklund, 1983; Ronco et al., 1992) showed inconclusive results, and often did not control for confounding variables. Two other epidemiological studies based on the same three cases (Saracci et al., 1991; Coggon D., Pannett B., Winter P.D., Acheson E.D., Bonsal J., 1986. Mortality of workers exposed to 2 methyl-4-chlorophenoxyacetic acid. Scandinavian Journal of Work, Environment, and Health 12:448-454) and one case-control study (Hardell L., Johansson B., Axelson O., 1982. Epidemiological study of nasal and nasopharyngeal cancer and their relation to phenoxy acid or chlorophenol exposure. American Journal of Industrial Medicine 3:247-257) showed increased risk associated with herbicide exposure; however, that risk was not statistically significant, which diminshes the importance of these studies. Accordingly, the Secretary has found that the credible evidence against an association between nasal

nasopharyngeal cancers and herbicide exposure outweighs the credible evidence for such an association, and he has determined that a positive association does not exist.

NAS also reviewed the literature with respect to possible assocations between herbicide exposure and various reproductive effects, i.e., spontaneous abortion, birth defects, neonatal infant deaths and stillbirths, low birth weight, and childhood cancers in offspring. These reproductive effects were categorized by NAS as health outcomes with inadequate/insufficient evidence to determine whether an association exists because the studies were of inadequate statistical power for specific birth defects, contained a limited sample size, and/or failed to exclude bias and chance. It should be noted that to compensate a veteran for these conditions is beyond VA's authority (See title 38, U.S.C.) and would require enabling legislation.

NAS assigns four diseases or categories of diseases to a category labeled limited/suggestive evidence of no association with herbicide exposure which it defined as meaning that several adequate studies, covering the full range of levels of exposure that humans are known to encounter, are mutually consistent in not showing a positive association between herbicide exposure and the particular health outcome at any level of exposure. The conditions include skin cancer, gastrointestinal tumors (stomach cancer, pancreatic cancer, colon cancer, and rectal cancer), bladder cancer, and brain tumors. There were many credible studies (See NAS Report, Chapter 8) concerning all of these conditions that showed no association or a negative association with herbicide exposure. Accordingly, the Secretary has found that there is no credible evidence for an association between skin cancer, gastrointestinal tumors (stomach cancer, pancreatic cancer, colon cancer, and rectal cancer), bladder cancer, and brain tumors and herbicide exposure, and he has determined that a positive association does not exist.

NAS reviewed approximately 6,420 abstracts of scientific or medical articles as an integral part of the process that resulted in its report, entitled "Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam." From these articles, approximately 230 epidemiologic studies, including studies of people exposed to herbicides in occupational and environmental settings as well as studies of Vietnam veterans, were chosen for detailed review and analysis. In our judgment the comprehensive review and evaluation of the available literature which NAS conducted in conjunction with its report has permitted us to identify all conditions for which the current body of knowledge supported finding of an association with her exposure. Accordingly, the Secretary has determined that there is no positive association between exposure to herbicides and any other condition which he has not specifically determined that a presumption of service connection is warranted.

Dated: December 22, 1993.

Jesse Brown,

Secretary of Veterans Affairs.

[FR Doc. 94-73 Filed 1-3-94; 8:45 am]

APPENDIX C

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

94-7050

JENNIE R. LEFEVRE, SALLY M. HILL, FREDERICK L. RADA and CHRISTINA VELDMAN,
Petitioner,

v.

SECRETARY, DEPARTMENT OF VETERANS AFFAIRS,
Respondent.

ORDER

Before RICH, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and MICHEL, Circuit Judge.

A petition for rehearing having been filed by the PETITIONER,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED.

The mandate of the court will issue on November 6, 1995 unless another time becomes appropriate under Rule 41.

Dated: October 13, 1995

FOR THE COURT,
FRANCIS X. GINDHART,
Clerk

by /s/ Diane M. Frye
DIANE M. FRYE
Chief Deputy Clerk

[Filed Oct. 13, 1995]

APPENDIX D

STATUTE INVOLVED

§ 1116. Presumptions of service connection for diseases associated with exposure to certain herbicide agents

(a)(1) For the purposes of section 1110 of this title, and subject to section 1113 of this title

> (A) a disease specified in paragraph (2) of this subsection becoming manifest as specified in that paragraph in a veteran who, during active military, naval, or air sevice, served in the Republic of Vietnam during the Vietnam era; and
>
> (B) each additional disease (if any) that (i) the Secretary determines in regulations prescribed under this section warrants a presumption of service-connection by reason of having positive association with exposure to an herbicide agent, and (ii) becomes manifest within the period (if any) prescribed in such regulations in a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the Vietnam era and while so serving was exposed to that herbicide agent.

shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of evidence of such disease during the period of such service.

(2) The diseases referred to in paragraph (1)(A) of this subsection are the following:

> (A) Non-Hodgkin's lymphoma becoming manifest to a degree of disability of 10 percent or more.
>
> (B) Each soft-tissue sarcoma becoming manifest to a degree of disability of 10 percent or more other than osteosarcoma, chondrosarcoma, Kaposi's sarcoma, or mesothelioma.

(C) Chloracne or another acneform disease consistent with chloracne becoming manifest to a degree of disability of 10 percent or more within one year after the last date on which the veteran performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(D) Hodgkin's disease becoming manifest to a degree of disability of 10 percent or more.

(E) Porphyria cutanea tarda becoming manifest to a degree of disability of 10 percent or more within a year after the last date on which the veteran performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(F) Respiratory cancers (cancer of the lung, bronchus, larynx, or trachea) becoming manifest to a degree of 10 percent or more within 30 years after the last date on which the veteran performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(G) Multiple myeloma becoming manifest to a degree of disability of 10 percent or more.

(3) For the purposes of this subsection, a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the Vietnam era and has a disease referred to in paragraph (1)(B) of this subsection shall be presumed to have been exposed during such service to an herbicide agent containing dioxin or 2,4-dichlorophenoxyacetic acid, and may be presumed to have been exposed during such service to any other chemical compound in an herbicide agent, unless there is affirmative evidence to establish that the veteran was not exposed to any such agent during that service.

(4) For purposes of this section, the term "herbicide agent" means a chemical in an herbicide used in support

of the United States and allied military operations in the Republic of Vietnam during the Vietnam era.

(b)(1) Whenever the Secretary determines, on the basis of sound medical and scientific evidence, that a positive association exists between (A) the exposure of humans to an herbicide agent, and (B) the occurrence of a disease in humans, the Secretary shall prescribe regulations providing that a presumption of service connection is warranted for that disease for the purposes of this section.

(2) In making determinations for the purpose of this subsection, the Secretary shall take into account (A) reports received by the Secretary from the National Academy of Sciences under section 3 of the Agent Orange Act of 1991, and (B) all other sound medical and scientific information and analyses available to the Secretary. In evaluating any study for the purpose of making such determinations, the Secretary shall take into consideration whether the results are statistically significant, are capable of replication, and withstand peer review.

(3) An association between the occurrence of a disease in humans and exposure to an herbicide agent shall be considered to be positive for the purposes of this section if the credible evidence for the association is equal to or outweighs the credible evidence against the association.

(c)(1)(A) Not later than 60 days after the date on which the Secretary receives a report from the National Academy of Sciences under section 3 of the Agent Orange Act of 1991, the Secretary shall determine whether a presumption of service connection is warranted for each disease covered by the report. If the Secretary determines that such a presumption is warranted, the Secretary, not later than 60 days after making the determination, shall issue proposed regulations setting forth the Secretary's determination.

(B) If the Secretary determines that a presumption of service connection is not warranted, the Secretary, not later than 60 days after making the determination, shall publish in the Federal Register a notice of that determination. The notice shall include an explanation of the scientific basis for that determination. If the disease already is included in regulations providing for a presumption of service connection, the Secretary, not later than 60 days after publication of the notice of a determination that the presumption is not warranted, shall issue proposed regulations removing the presumption for the disease.

(2) Not later than 90 days after the date on which the Secretary issues any proposed regulations under this subsection, the Secretary shall issue final regulations. Such regulations shall be effective on the date of issuance.

(d) Whenever a disease is removed from regulations prescribed under this section—

(1) a veteran who was awarded compensation for such disease on the basis of the presumption provided in subsection (a) before the effective date of the removal shall continue to be entitled to receive compensation on that basis; and

(2) a survivor of a veteran who was awarded dependency and indemnity compensation for the death of a veteran resulting from such disease on the basis of such presumption shall continue to be entitled to receive dependency and indemnity compensation on such basis.

(e) Subsections (b) through (d) shall cease to be effective 10 years after the first day of the fiscal year in which the National Academy of Sciences transmits to the Secretary the first report under section 3 of the Agent Orange Act of 1991.

CREDIT(S)

1991 Main Volume

(Added Pub.L. 102-4, § 2(a)(1), Feb. 6, 1991, 105 Stat. 11, § 316, renumbered and amended Pub.L. 102-83, § 5(a), (c)(1), Aug. 6, 1991, 105 Stat. 406.)

1995 Interim Update

(As amended Pub.L. 103-446, Title V, § 505, Title XII, § 1201(e)(6), Nov. 2, 1994, 108 Stat. 4664, 4685.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1991 Act. Statement by President, see 1991 U.S. Code Cong. and Adm.News, p. 11.

1994 Acts. Related House Report No. 103-669, see 1994 U.S. Code Cong. and Adm. News, p. 3681.

References in Text

Section 3 of the Agent Orange Act of 1991, referred to in subsecs. (b)(2), (c)(1)(A), and (e), is section 3 of Pub.L. 102-4, Feb. 6, 1991, 105 Stat. 13, which is set out as a note under section 1154 of this title.

Amendments

1994 Amendments. Subsec. (a)(1)(B). Pub.L. 103-446, § 1201(e)(6), redesignated provisions formerly designated as pars. (1) and (2) of subpar. (B) as cls. (i) and (ii) of subpar. (B), respectively.

Subsec. (a)(2)(D) to (G). Pub.L. 103-446, § 505, added subpars. (D) to (G).

1991 Amendment. Subsec. (a)(1). Pub.L. 102-83, § 5(c)(1), substituted "1110" for "310" and "1113" for "313".

Agent Orange Study; Report to Congressional Committees

Pub.L. 96-151, Title III, § 307, Dec. 20, 1979, 93 Stat. 1097, as amended by Pub.L. 97-72, Title IV, § 401, Nov. 3, 1981, 95 Stat. 1061; Pub.L. 98-542, § 8(a), Oct. 24, 1984, 98 Stat. 2731, directed that a protocol be designed for an epidemiological study of the long term health effects of agent orange on armed forces personnel who served in Vietnam, and that reports be submitted to Congress describing results with comments and recommendations.

Agreement With National Academy of Science for Review and Evaluation Regarding Associations Between Diseases and Exposure to Dioxin and Other Chemical Compounds in Herbicides Used in Vietnam

Section 3 of Pub.L. 102-4, as amended Pub.L. 102-86, Title V, § 503(a), (b)(1), Aug. 14, 1991, 105 Stat. 424, 425, provided that:

"(a) Purpose.—The purpose of this section is to provide for the National Academy of Sciences, an independent nonprofit scientific organization with appropriate expertise which is not part of the Federal Government, to review and evaluate the available scientific evidence regarding associations between diseases and exposure to dioxin and other chemical compounds in herbicides.

"(b) Agreement.—The Secretary shall seek to enter into an agreement with the National Academy of Sciences for the Academy to perform the services covered by this section. The Secretary shall seek to enter into such agreement not later than two months after the date of the enactment of the Veterans' Benefits Programs Improvement Act of 1991 [Aug. 14, 1991].

"(c) Review of scientific evidence.—Under an agreement between the Secretary and the National Academy of Sciences under this section, the Academy shall review and summarize the scientific evidence, and assess the strength thereof, concerning the association between exposure to an herbicide used in support of the United

States and allied military operations in the Republic of Vietnam during the Vietnam era and each disease suspected to be associated with such exposure.

"(d) Scientific determinations concerning diseases.—(1) For each disease reviewed, the Academy shall determine (to the extent that available scientific data permit meaningful determinations)—

"(A) whether a statistical association with herbicide exposure exists, taking into account the strength of the scientific evidence and the appropriateness of the statistical and epidemiological methods used to detect the association;

"(B) the increased risk of the disease among those exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and

"(C) whether there exists a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the disease.

"(2) The Academy shall include in its reports under subsection (g) a full discussion of the scientific evidence and reasoning that led to its conclusions under this subsection.

"(e) Recommendations for additional scientific studies.—The Academy shall make any recommendations it has for additional scientific studies to resolve areas of continuing scientific uncertainty relating to herbicide exposure. In making recommendations for further study, the Academy shall consider the scientific information that is currently available, the value and relevance of the information that could result from additional studies, and the cost and feasibility of carrying out such additional studies.

"(f) Subsequent reviews.—An agreement under subsection (b) shall require the National Academy of Sciences—

"(1) to conduct as comprehensive a review as is practicable of the evidence referred to in subsec-

tion (c) that became available since the last review of such evidence under this section; and

"(2) to make its determinations and estimates on the basis of the results of such review and all other reviews conducted for the purposes of this section.

"(g) Reports.—(1) The agreement between the Secretary and the National Academy of Sciences shall require the Academy to transmit to the Secretary and the Committees on Veterans' Affairs of the Senate and House of Representative periodic written reports regarding the Academy's activities under the agreement. Such reports shall be submitted at least once every two years (as measured from the date of the first report).

"(2) The first report under this subsection shall be transmitted not later than the end of the 18-month period beginning on the date of the enactment of this Act [Feb. 6, 1991]. That report shall include (A) the determinations and discussion referred to in subsection (d), (B) any recommendations of the Academy under subsection (e), and (C) the recommendation of the Academy as to whether the provisions of each of sections 6 through 9 [sections 6 through 9 of Pub.L. 102-4, set out as notes under this section] should be implemented by the Secretary. In making its recommendation with respect to each such section, the Academy shall consider the scientific information that is currently available, the value and relevance of the information that could result from implementing that section, and the cost and feasibility of implementing that section. If the Academy recommends that the provisions of section 6 [section 6 of Pub.L. 102-4, set out as a note under this section] should be implemented, the Academy shall also recommend the means by which clinical data referred to in that section could be maintained in the most scientifically useful way.

"(h) Limitation on authority.—The authority to enter into agreements under this section shall be effective for

a fiscal year to the extent that appropriations are available.

"(i) Sunset.—This section shall cease to be effective 10 years after the last day of the fiscal year in which the National Academy of Sciences transmits to the Secretary the first report under subsection (g).

"(j) Alternative contract scientific organization.—If the Secretary is unable within the time period prescribed in subsection (b) to enter into an agreement with the National Academy of Sciences for the purposes of this section on terms acceptable to the Secretary, the Secretary shall seek to enter into an agreement for the purposes of this section with another appropriate scientific organization that is not part of the Government and operates as a not-for-profit entity and that has expertise and objectivity comparable to that of the National Academy of Sciences. If the Secretary enters into such an agreement with another organization, then any reference in this section and in section 316 of title 38, United States Code (as added by section 2) [section 316 of this title], to the National Academy of Sciences shall be treated as a reference to the other organization."

"(k) Liability insurance.—(1) The Secretary may provide liability insurance for the National Academy of Sciences or any other contract scientific organization to cover any claim for money damages for injury, loss of property, personal injury, or death caused by any negligent or wrongful act or omission of any person referred to in paragraph (2) in carrying out any of the following responsibilities of the Academy or such other organization, as the case may be, under an agreement entered into with the Secretary pursuant to this section:

"(A) The review, summarization, and assessment of scientific evidence referred to in subsection (c).

"(B) The making of any determination, on the basis of such review and assessment, regarding the

matters set out in clauses (A) through (C) of subsection (d)(1), and the preparation of the discussion referred to in subsection (d)(2).

"(C) The making of any recommendation for additional scientific study under subsection (e).

"(D) The conduct of any subsequent review referred to in subsection (f) and the making of any determination or estimate referred to in such subsection.

"(E) The preparation of the reports referred to in subsection (g).

"(2) A person referred to in paragraph (1) is—

"(A) an employee of the National Academy of Sciences or other contract scientific organization referred to in paragraph (1); or

"(B) any individual appointed by the President of the Academy or the head of such other contract scientific organization, as the case may be, to carry out any of the responsibilities referred to in such paragraph.

"(3) The cost of the liability insurance referred to in paragraph (1) shall be made from funds available to carry out this section.

"(4) The Secretary shall reimburse the Academy or person referred to in paragraph (2) for the cost of any judgments (if any) and reasonable attorney's fees and incidental expenses, not compensated by the liability insurance referred to in paragraph (1) or by any other insurance maintained by the Academy, incurred by the Academy or person referred to in paragraph (2), in connection with any legal or administrative proceedings arising out of or in connection with the work to be performed under the agreement referred to in paragraph (1). Reimbursement of the cost of such judgments, attorney's

fees, and incidental expenses shall be paid from funds appropriated for such reimbursement or appropriated to carry out this section, but in no event shall any such reimbursement be made from funds authorized pursuant to section 1304 of title 31, United States Code."

* * * *